Expert Report on Health Care Systems

by

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Designated Confidential - Subject to a Protective Order

Pursuant to Rule 26(a) of the Federal Rules of Civil Procedure, the undersigned Gio Wiederhold, PhD., submits this report and declares the following to be a summary of his opinions to be offered under oath in this matter.

I am a fellow of the American College of Medical Informatics (since 1984), the Association for Computing (since 1995), and the Institute of Electrical and Electronic Engineers (since 1991). Attached, as Appendix A is a copy of my curriculum vitae, including my published writings in the last ten years.

I have previously testified and given a deposition once, 21 August 1998, on the case of Cadence versus Avant! Corporation, Case C95-220828-RMW, U.S District Court for the Northern District of California.

My hourly consulting rate is $250 per hour. This rate applies to time spent reviewing documents, consulting on issues and cases, conducting analyses, advising on technology and methods in system design and implementation, preparing reports and testifying as needed in deposition and at trial.

In addition to considering my own knowledge and experience, the attached bibliography summarizes the material reviewed for usage in this report including: previous expert reports, depositions, exhibits, the patent-in-suit as well as other patents, the prosecution history of the patent-in-suit, claim construction charts, brochures, articles, books, declarations, medical dictionaries, other dictionaries, the web, Trigon employee interviews, phone conversations, conversations with colleagues and their assistance, and many other sources.

I will continue to review new information and reserve the right to amend, supplement, or modify opinions expressed in this report if it becomes necessary when presented with additional material or information.

Respectfully submitted,

Gio Wiederhold, Date: December 20, 2002.

Introduction

This report presents an analysis of the validity of US patent 5,301,105 (`105), asserted by Allcare Health Management systems, Inc. ("Allcare"), the plaintiff in a civil action number 1:02CV756-A. According to the abstract, the '105 patent relates to "A Fully Integrated and Comprehensive Health Care System ... ". The description provided with the Figures call it a "Wellness Health Management System", and the claims have preambles that refer to "A Comprehensive Health Care Management System" (63 times), "An Integrated Health Care Management System" (10 times) and omit the qualification in the remaining claims. The report subsequently compares the claimed features of the `105 patent with the systems operated by the defendants, a Claims Reimbursement System.

In my opinion, the `105 patent is seriously flawed. If the `105 patent would be upheld, then it would still not be infringed by the defendants' systems. Because of the errors and vagueness in the `105 patent, the claims do not serve as notice of what is within and without the scope. The basis and opinions presented in Section 1 of this report, namely Patent Invalidity, hence arise also in Section 2, Non-infringement.

The 102 claims in the `105 patent specify much narrower systems than the specifications preceding them (See also Section 5.5.2). The 102 claims all relate to automating control of reimbursement based on patient complaints and medical history, although the preambles of the claims often state that such a system represents a comprehensive health care system (See Section 3.12). The specifications, primarily in the major section Preferred Embodiment, describe an implementation never realized anywhere, neither by the plaintiff, nor by the defendant, nor by any other organization or government. The confusion between description, claims, and feasibility becomes clear when perusing reports presented by the plaintiff, say, [Singer:2000], as indicated in Section 5.4 . The plaintiff's experts link the `105 claims to carefully selected items of the specification in a fashion that implicates systems in a way very different from the technology actually described in the `105 patent.

Of course, the idea of an all-encompassing health care system is not new. In Section 4.3.1 we cite the long-term view, published in 1984, of an expert actually building Health Care Systems [Halverson:1984]. Halverson recognizes that eventually we will need smart, artificial intelligence systems. He did not patent that vision because he did not know how to build such a system either. Research to achieve that vision had been ongoing for many years and continues to make slow progress [Wiener: 1960]. If the claims of the `105 were to be construed as asserted by Plaintiff, then there is nothing to distinguish the claim coverage from most of health care data processing, including manual, paper, phone, fax and computer-based, past and present. The coverage would extend to systems built in the past and systems built after the patent was issued, as well as to systems one might build in the future, including results of ongoing research.

The vagueness of the patent requires that we present a Section 3, Definitions. The text in this report uses these definitions throughout. Our definitions hew closely to widely accepted standards in the health care systems community. Since questions of originality have been raised, we also provide in Section 4 some brief reviews of systems that carry out similar functions as those claimed in the `105 patent. In Section 5 we analyze and rebut some of the testimonies provided by the plaintiff. A list of further references closes the body of this report.

Appendices expand on the following topics:
A. My vitae and a reduced biography
B. Symptoms Misused as Diagnoses in Plaintiff Testimony
C. Definitions of Medical Terms used in the report and in relevant testimonies
D. Claims clusters to structure the `105 patent
E. Materials made available and reviewed.

1. The `105 Patent is Invalid.

This section sets forth issues that we have with the granting of the patent in the first place.

This patent was granted without verification that critical concepts implied in its claims and in its specification were enabled or even understood by the patent applicant. In each of the claims, there is an assumption that a `smart system' can fill a gap in the process that is required to perform the recited functions and methods. The term `smart system' appears in Figures 1 and 6 and seven times in the preferred embodiment section of the specification (See Section 1.5), but no further indication of the construction, technology, or the methods that might be used to build such a `smart system' is provided. It is infeasible to implement the claims as stated. Implementing the specified vision is similarly infeasible.

Since even today, 12 years later, no `smart systems' nor other systems exist that can carry out the scope of the tasks envisioned by the `smart systems' of the `105 patent, it is neither possible to operate within the scope of the patent nor to show prior art to demonstrate the features claimed in the `105 patent. The patent applicant did not claim to have invented such a 'smart system' either. He simply states that he believes that such a smart system is possible, or that it can be obtained from public sources, see Section 5.1.4.

In summary, the error made in granting the `105 patent is the failure to recognize that it is infeasible as the specification is not sufficient to enable one of ordinary skill in the art to practice the invention without undue experimentation, if at all. We understand that Allcare has asserted that a 'smart system' according to the '105 patent need not exhibit the afore referenced capacity and have, therefore, assumed a construction as asserted by Allcare for the purpose of comparison of the claims to the prior art.

Now on to the specifics.

1.1 Discontinuity in the Linkage from Symptoms to Treatment

The `105 patent depends for its effectiveness on automatically making correct decisions about appropriate treatment based on patient symptoms " ... input of data through said input means symbolic of symptoms of one of said predetermined plurality of persons for tentatively identifying a proposed mode of treatment ... " [`105: claim 1(d)]. Those symptoms (see Definition 3.1) are to be entered by the physician (claims 1, 2, 4, 16, 17, 19, 34, 52, 67, 70, and 102 and their associated dependent claims) or sometimes (claim 85 and the associated dependent claims) are to be available as part of a Medical History (see Definition 3.7).

Symptoms are the external manifestations of a possible disease presented by a patient to a health care provider. The most common symptom presented by a patient is pain [Blois:1984]. It is up to the physician, using education and experience, to further examine the patient and arrive at a diagnosis (see Definition 3.3). Kaliski, a computer science

expert examining the `105 patent, consistently equates symptoms to diagnoses [Kaliski:2002, p.18, and footnote 18 on page 32], taking [Holland:2002] as the authority (see also Section 1.1.3). However, Holland, in justifying the equivalence, avoids citing applicable literature and instead relies on a misleading example (see Section 5.6). The fallacy of equating symptoms to diagnoses is addressed in detail in Sections 5.5.4 and 5.7, but should be obvious to any one who has presented clear symptoms to a doctor and watched the often tedious process of arriving at a diagnosis.

The patent specifications do not make that error. The `105 patent provides ‘smart systems' and ‘expert systems' to make that transformation (see Section 1.1.1).

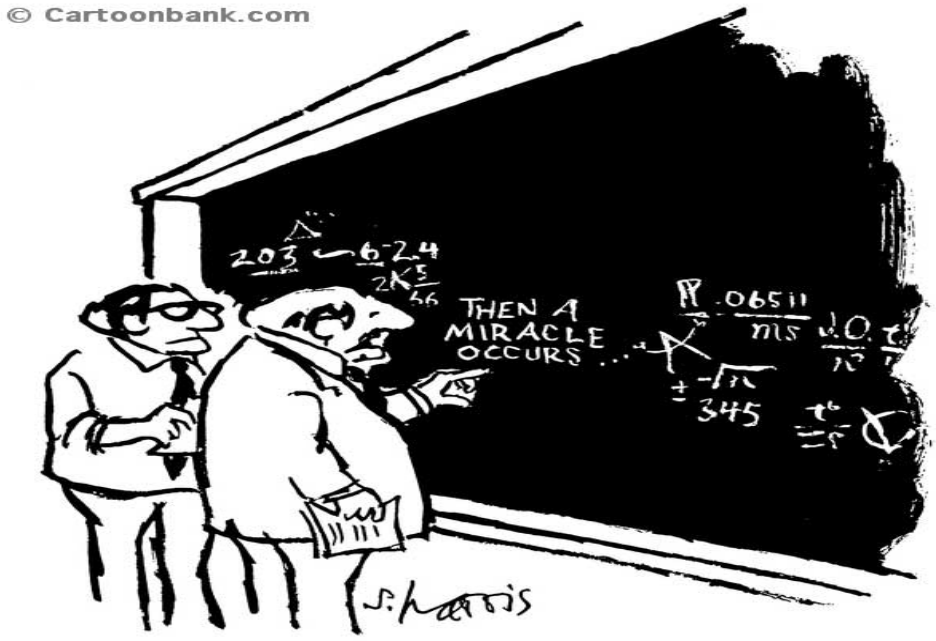
> Figure 1, label 21: Smart system, drugs, and diagnostics
>
> Figure 6: "An expert system that compares diagnostics test - line attendance based on physician goal and patient history"
>
> Column 2, line 34: "physician interaction via smart system"
>
> Column 5, line 10: smart system (diagnosis and drugs)
>
> Column 6, lines 55-70: "In accordance with the "Smart System" characteristics of the invention, Physician File 44 preferably will include an identification of the most commonly encountered diseases and other ailments, together with symptoms usually associated therewith. Accordingly, if symptoms are entered into the system terminal (e.g., one of terminals 11a-11c), and an identification of the corresponding illness is requested from the Processing System 10, the physician's file is interrogated, and the system prepares a list of the most likely medical condition corresponding to such symptoms, together with the generally approved and/or recommended treatment protocols. It also contemplates the identification within Physician File 44 of those procedures for which Utilization Review and/or Second Opinion 34 is deemed necessary or desirable. "
>
> Column 9, lines 53-65: "By this is contemplated the entry of symptoms and other data which can assist in making a diagnosis and identifying the aforementioned recommended treatment protocols. Thus, the physician is assisted in correlating the observed patient symptoms and test results so as to identify the most likely causes of the health problem, complete his diagnosis, and prescribe the most appropriate treatment protocols."
>
> Column 10, starting at line 24:"An Expert System that Compares Diagnostic Testline Attendance Based on Physician goal and Patient History." Thus, the physician is able to determine the testing options based on conditions and the condition of the body that each test was designed to report on. In addition, the physician is given the cost of each testing procedure including those that are laboratory or radiology based. If requested, the system will allow the physician to

select through a triage process to determine what test would yield the best data for diagnosis of the presenting problem. "

The fact that the patent does not say how the process of inferring diagnoses from symptoms might work does not mean that symptoms are to be confused with diagnoses. The author of the `105 patent himself has stated that the two concepts are distinct (See Section 5.1.2).

Treatments (see Definition 3.5) are the means to cure diseases. The intent of the mechanisms and methods described in the `105 claims in general is to prevent payment for treatments that are not warranted for the patients presenting certain symptoms.

The mechanisms and methods presented in the `105 patent claims fail to make a clear and implementable connection from symptoms to treatments. Making such a connection automatically is well beyond the state of the art, and hence presents a serious discontinuity in the `105 patent. Elaboration on this issue is set forth in Section 3 of this report.



"I think you should be more explicit here in step two."

In defending the validity of the `105 patent, Allcare has presented three distinct arguments:

1. Smart systems were available at the time that the `105 patent was applied for that could bridge the discontinuity automatically
2. The `105 patent allows human experts to intercede and bridge the discontinuities that cannot be handled by computer programs.
3. What is actually entered by the physicians are diagnoses, and not symptoms.

These three arguments do not complement each other. We will discuss them distinctly.

1.1.1 Automatic Diagnosis and Treatment from Symptoms.

When faced with the challenge of linking symptoms to treatments during earlier depositions, [Cummings II:2000, p. 186, l. 17-21] [Cummings II:2000, p. 218 l. 24-25] [Cummings II:2000, p. 219, l. 1-7], Cummings claimed that a `smart system' can bridge such a discontinuity, without citing any actual 'smart system' that did or could perform that task. I expand on the lacunae in Section 5.1.3 As a reference for his belief, Cummings cites a Health Risk Assessment system developed within his organization, but not by him [Cummings:2002, p.145] (see Section 3.26 for a definition) Cummings also claimed in those depositions that a routine statistical procedure, namely factor analysis, could provide the parameters needed by such a `smart system'. We also present an analysis of the inadequacy of factor analysis for this task in that section. Since 'wellness', rather than management of disease has been the primary interest of the patent holder, he uses his experience with Health Risk Assessments (HRA) as a model for disease management in a Comprehensive Health Care System without considering the problems of moving into a domain with a much larger scope and risks, a domain that demands medical certification.

The fallacy of the possible existence of such a `smart system' is that it requires automation of the physician's art. While such an advance is imaginable, it has not been achieved, it has not been shown that it is achievable, and has certainly not been achieved by the plaintiff.

That this patent has been granted is likely due to two factors:

1. The lack of an explicit `smart system' step in the claims appears to have led to the patent examiner ignoring the failure of the specification to teach how to make and use any such system, i.e., the existence of a gap in the process. It is hard for an examiner to find fault with issues that have not been described.
2. The specification does not set forth sufficient information about medicine and medical diagnostic techniques to have alerted the patent examiner to the unfeasibility of the approach.

The issuance and attempt to enforce the `105 patent against Defendants on the basis of automation of the diagnostic process is analogous to patenting passenger flights to Mars and enforcing the resulting patent against airlines operating domestic passenger service.

1. There have been earlier science fiction stories and projections about flights to Mars.
2. Others have made experimental flights to the moon.
3. A patent application discloses the concept of planetary travel, describing the process of boarding and disembarking, and flying above the surface of a planet, and indicate that a smart vehicle can make the trip, without specifying it in detail or having ever flown to Mars.
4. Since all travel above the surface of one planet is included in that concept, the patentee can now collect licensing fees from all airlines.

The strategy of extracting license fees has been explicitly stated in a letter by Charles Singer to Robert Shelton and Halden Conners [Singer:2000D, exhibit 20 (AHM 02578/AHM0334634)]:

> "Bradley .. felt that United Healthcare might fight this on principle, as opposed to just paying the fee. ... the strategy of going for the weaker and smaller organizations as licensees to add validity looks like it is still the best."

and [ibid, exhibit 21, AHM 02800/AHM034687]

> "Their web sites are www.HBOC.com and www.epicsys.com. You can see from their web sites that they have broad portfolios of applications and customers, and their claims are right on target as dream infringers."

Nowhere in that correspondence is there any indication of a beneficial deliverable to be provided to the potential licensees.

1.1.2 Manual Diagnosis and Treatment from Symptoms.

Diagnosing a patient's disease from symptoms, signs and a medical history by human experts is feasible. That is what clinicians are trained to do, and do quite well after many years of training. However, if we allow the patent to cover manual process steps as well as automated process steps, there is a wealth of prior art that is applicable and has not been cited. All the prior art cited in the `105 patent and prosecution history describes fully automated systems (see Section 5). We summarize the patents brought forth as prior art briefly in Section 5.10 to 5.17.

The specification does mention "physician interaction via smart systems", [`105: c. 2 l. 34] but in the specific section of interest (see also this Report, Section 1.2) the `105 patent states specifically:

> Accordingly, if symptoms are entered into the system terminal (e.g., one of terminals 11a-11c), and an identification of the corresponding illness is requested from the Processing System 10, the physician's file is interrogated, and the system prepares a list of the most likely medical condition corresponding to such symptoms, together with the generally approved and/or recommended treatment protocols. [`105: c. 6 l. 59-67]

The author of the `105 patent, in a deposition, states that he believes that the `105 patent also covers arbitrary replacement of automation by manual processing steps. For instance, in [Cummings I 2000, p. 142, l. 6-24] he states in the context of Claim 1 of the patent that :

> Well, I think if you read through it, it also says it could be manual. So there is manual capabilities, as well as automated capabilities.
> Q: Okay, Well --
> A: Or automated --
> Q: So Claim 1, to you, covers both manual systems and automated systems, correct?
> A: Right.
> Q: Okay. And a manual system does not have electronic communications between the patient, health care provider, bank or other financial institution, insurance company, utilization reviewer and employer, correct?
> A: I think it's -- that's a technical decision I think that, you know, the telephone is a manual system, but it can be utilized with some automated properties. So it can be technically -- so I'd say that with that qualification, fax, telephone, those require certain manual -- whereas a computer's all automated.

on page 143, lines 24-25:

> In the [`105] patent process, there is data sending and there is human intervention.

on page 145 lines 2-4 in responding to:

> Q: do you envision that possibly being done with people talking to each other on the phone:
> A: In a primitive situation if necessary. Could be. I don't really -- the vision is to get all electronic

This latter statement even implies that the `105 patent could cover 100% manual processing of healthcare and claims reimbursements. By that definition, the `105 patent covers all existing prior art, since before computers ("BC" being about 1950), all such processing was being performed manually, on paper and by telephonic communication. Even today there is a work force of humans that look at the claims (CHIPS and TRIMED staff for example) within a reimbursement claims workflow system which is made up of a combination of automated computational and human-based manual processing.
Singer performed a search for prior art, which ignored any system that was not fully automated. His recent depositions have been consistent with that view. For instance, Singer has stated (see Section 5.3.3), that the OPTIMED system does not constitute prior art, because it employs phone conversations, rather than "electronic communication means as required by the patent" [Singer:2000, p. 12].

Also, "in the 105 patent .. communication of this [patient] data to the UR [(Utilization Review)] firm is clearly intended to occur as computerized data." [ibid, page 11].

The steps of paramount concern regarding the substitution of human experts where the `105 patent cannot show that automation was achievable are:

> **Diagnosis:** Establishing a diagnosis is the first step required when selecting a treatment based on patient symptoms. That task is central to the art of medicine. Establishing a diagnosis (see Definition 3.3), takes into account many factors that go beyond the symptoms presented by the patient. Physicians have had to diagnose patients based on presented symptoms since Aesculapius: *Ad sanitatem gradus est novisse morbum* (The first step toward cure is to know what the disease is). We analyze the patent specifications and claims in regard to that step in detail in the subsequent Section 1.1. Simply stated, an automated system is not currently available.
>
> **Adjudication:** Deciding if a treatment is appropriate requires commensurate knowledge. In the `105 process this step is specific to the payment process. Since adjudication of reimbursement claims requires medical insight, professionals with medical degrees are employed to make the final decision. Simple eligibility rules are automated, routine and low cost treatments are not scrutinized, medications may be substituted, but any questionable cases (at TRIGON still a very large proportion) are handled manually, and often require telephonic interaction with the requesting health care provider. Automation of this step would be irresponsible, causing worthy patients to be denied treatment, while others that are able to *game* the system would be able to receive more treatment than is warranted.

Many expert's reports submitted for this case follow a generalization which allows physicians to convert symptoms manually to diagnoses and treatment recommendations. They also allow TRIGON's medical directors to make telephone calls to physicians' offices to obtain medical records, history information, and the like, all within the scope of the `105 patent. Their extrapolations of the claims as written are either due to lack of knowledge of health care [e.g., Kaliski:2002], or an excess of knowledge. If an expert assumes that the patent is valid because the question posed is one of infringement, then the expert will impose his or her knowledge upon the system, and, for instance, consider that `diagnosis' is meant where `symptom' was written [e.g., Holland:2002].

The `105 patent cannot allow the substitution of automated, computer-based processing by manual handling, carried out by medical or nursing staff. For instance, when discussing telephonic communication as an alternative by a provider with a 'Utilization Review Company' to obtain permission for an inpatient admission [Singer I:2000, p.82]:

> was the normal mode at the time this patent was written and so to specify a system like that would make no sense, because that, in fact, was what they were trying to fix. [p. 82 1.14-15]

If substitution by manual processing at any step of the `105 process were allowed, the entire house of cards that is the '105 patent would fall because there would be no distinction between the whole gamut of prior art. Indeed, such manual operations have been ongoing for many years in healthcare. Predecessors of TRIGON had to validate eligibility for reimbursement for decades, ever since health care insurance was instituted

[MetropolitianLife:1985]. The prior art cited in the prosecution history of the patent deals only with automated systems, systems in which there are no intermediary manual processes. We could not locate in the prosecution history any reference to manual processes. The citation of only fully automated prior art indicates that both the applicant and the Examiner, at the time of examination, contemplated only fully automated systems..

1.1.3. Symptoms are NOT Equal to Diagnoses.

Plaintiff's Experts fall into the trap of making assumptions that would allow resolution of the problem that this patent presents. The most common trap is that symptoms are the same as diagnoses. We will first cite evidence and testimony that symptoms are not equal to diagnoses, and then show why the arguments that equate them are false.

Symptoms are not equal to diagnoses. Dictionaries, the patent itself, the author of the `105 patent, and the healthcare expert at Allcare all distinguish symptoms and diagnoses:

First we refer to the definitions in Section 3.1 and 3.3 of this report, taken from general as well as from medical dictionaries that clearly distinguish the two, symptoms being complaints presented by the patient to a health care provider, and diagnoses being determined by a health care provider based on reported symptoms, signs observed by the physician or through clinical testing (see Definition 3.2), and the patients medical history (see Definition 3.7).

Dependent Claims 13, 28, and 44 of the `105 patent introduce a databank to provide information for the processing of symptoms to obtain diagnoses:

> Claim 13. A comprehensive health care management system according to claim 2 in which one of said databank memories includes identification of symptoms for diagnosis of each of a predetermined plurality of illnesses.

If symptoms were equal to diagnoses no such databank would be required. Claims 64 and 70 access such a databank to retrieve symptoms to aid in obtaining a diagnosis:

> Claim 64. A method of managing a health care management system according to claim 55 further including the step of accessing one of said databank memories to identify symptoms for diagnosis of each of a predetermined plurality of illnesses.

If symptoms were equal to diagnoses no such processing would be required; and finally, Claim 94 provides for entering of symptoms for diagnosis.

> Claim 94. A method of managing a health care management system according to claim 85 including the step of entering into said data bank memory an

> identification of symptoms for diagnosis of each of a predetermined plurality of illnesses.

If symptoms were equal to diagnoses none of these claim steps would be required.

In the specification of the `105 patent the physician file is described as being this symptom-diagnosis databank referred to in the claims:

> In accordance with the "smart system" characteristics of the invention, Physician File 44 preferably will include an identification of the most commonly encountered diseases and other ailments, together with symptoms usually associated therewith. [`105: c. 6 l. 55-59].

If symptoms were equal to diagnoses no such information would be required in the physician file. Finally, the difficulty of translating symptoms to diagnoses is emphasized in this sentence as being associated with the `smart system' characteristics of the `105 patent. We discussed those aspects in Section 1.1.1. Obviously no `smart system' would be required to help in this task if symptoms were equal to diagnoses.

[Cummings II.:2000, p. 182 l. 22-23] is initially also fairly clear that there is a difference.

> Symbolic of symptoms does not mean symbolic of diseases.

(For further supporting statements in this testimony see Section 5.1.2) .
But, later, when faced with the problem in the Claims, Cummings backpedals:

> Q: ... what's the difference between data symbolic of symptoms and symptoms for diagnosis?
> A: They're similar.
> Q: Are the same thing?
> A: Could be the same thing but not all - yeah.
> [Cummings III: 2000, p. 311 l. 17-21]

[Singer:2000D, p. 73] considers that an expert system might be able to translate symptoms to diagnoses, but also that such a capability would be fairly rare:

> Q: And where you would actually tell the system, `Here are the symptoms. Here's what the patient is presenting to us,' and the system would actually make suggestions about `Here are possible diagnoses'?
> A: That form of system is rare, but some people have attempted that.
> Q: And had some people attempted that prior to 1990?
> A: I believe so.
> [Singer:2000D, p. 73]

Research in this area includes Jack Mayer's work, starting actually around 1970 (See Section 4.6.2: The Internist System). It is the difficulty of making diagnoses that makes such systems rare, a difficulty that would not exist if symptoms were equal to diagnoses.

Symptoms are equal to Diagnoses. Well-meaning experts resolve the problem of the `105 patent in various ways: For instance, Kaliski, being a computer scientist, simply equates symptoms with diagnosis, ignoring the `105 specification and claims where the smart system performs the inferential step, and cites [Holland:2002] as the authority (see Section 5.5.4).

Holland [Holland:2002] mixes symptoms and diagnoses, in creative, but unjustifiable ways to resolve the problem of the patent containing tasks that cannot be carried automatically (see Section 5.6.2 for the required detail). All of the symptoms that Holland cites as also being diagnoses are not, and would never be acceptable as the basis for a reimbursement claim, the objective of delivering such information to Trigon (We provide information on every single one in Appendix B. Only a few pathognomonic symptoms determine diseases, and these are so rare that one certainly would not base a Comprehensive Health Care Systems on them.

Singer [Singer:2000, pp. 75-77] simply misreads the patent and assumes that the physician enters treatments, and the system suggests alternative treatments:

> ... my interpretation of this is that the physician or the person providing the care is entering the proposed mode of treatment. .... the system might respond by saying, `Well you might want to also do these other things.'

Now the problem is solved by ignoring symptoms altogether. More detail about this interpretation is given in Section 5.6.2. but note that it conflicts with Singer's understanding that expert systems might translate symptoms to diagnosis, cited above.

If even the plaintiff's experts come up with such different interpretations of how the `105 patent is to be implemented, we must conclude that the `105 patent did not provide notice to a person of ordinary skill to determine what is within the scope of the claims

The plaintiff's experts were not concerned with the validity of the `105 patent. By constructing feasible systems, for instance, systems where diagnoses instead of symptoms are entered, the novelty of the `105 patent is lost, since claims reimbursement based on diagnoses submitted by the providers has been in existence for a long time.

1.1.4 Summary.

No solution resolving the discontinuity in the linkage from symptoms to treatment is enabled.

1. Inferring diagnoses or treatments needed from symptoms presented by the patient cannot be performed automatically by processes specified or even implied in the `105 patent. No such technology available to the patent holder.

2. The lack of references to prior art disallows substitution of automation by manual or alternative operations. Health care staff performing diagnosis and adjudication functions cannot be covered by the patent.

My personal opinion is that we might have systems that correspond to the patent holder's vision in the far future. The vision has been developed and expounded since the 1960's. We are not there in 2002, and I don't expect we will be before 2044. At that point physicians would only be managers of medical knowledge, and all direct interaction with patients could cease. Fortunately, Trigon has a less ambitious role, validating payment requests for medical treatments to help in keeping our health care system solvent. Paying license fees for unjustified claims of inventions that do not contribute one whit to our knowledge or capabilities does not help our society.

Most of the remaining points in Section 1 of this report contribute detail to this argument, although some of them are sufficiently strong to demolish the '105 patent or many of its individual claims. We will now refine the issues. Some key definitions are provided in Section 3.

1.2 Lack of Available Technologies for Automation

The crucial `smart system' step required is buried within individual functions recited in the claims of the `105 patent. We will cite the entry from Claim 1, and emphasize the issue in boldface:

> (d) means in communication with said input means **responsive** to input of **data** through said input means **symbolic of symptoms** of one of said predetermined plurality of persons **for tentatively identifying a proposed mode of treatment** for said one of said predetermined plurality of persons and, when said proposed mode of treatment includes one of said predetermined procedures requiring utilization review, for producing indicia indicative thereof and for preventing payment therefor by said payment means until said utilization review has been obtained and data indicative thereof has been entered in said system.

The essential phrase: **"means responsive to input data symbolic of symptoms for tentatively identifying a proposed mode of treatment"** appears in Claim 1(d), Claim 2, Claim 4, Claim 16, Claim 17, Claim 19(e), Claim 34, Claim 52(c), Claim 53, Claim 54, Claim 55(d), Claim 65, Claim 66, Claim 67(e), Claim 70(f), Claim 85(e), and, implicitly, in their dependent Claims 2-3, 5, 7-12, 17-18, 20-27, 35-46, 56-66, 68-69, 71-81, and 86-96. A similar phrase "**input of patients' symptoms for displaying recommended treatments, for identifying recommended treatments**" occurs in Claims 47 and 97, affecting their dependent Claims 48-51 and Claims 98-101. The few remaining claims: 82-85 and 102 perform similar tasks depending on a medical history and a personal health profile and will be addressed in Section 1.4.

The structure to perform the function of the ‘means' claims supporting the process in the `105 patent of establishing treatment on the basis of symptoms presented by the patients, is omitted from the claims, but can be inferred from the specification and is described further in the deposition testimony as being implemented via:

1) file tables ("the physician's file is interrogated, and the system prepares a list of the most likely medical condition corresponding to such symptoms, together with the generally approved and/or recommended treatment protocols") [`105: c. 6 l. 63-67],
2) as being achieved through a `smart system' [Cummings II:2000, p. 186 l. 17-21 pp. 218 l. 24-25 pp. 219 l. 1-9]
3) achieved through an Expert System [`105: Figure 6 Box 123][`105: c. 10 l. 24], and
4) based on factor-analysis [Cummings II:2000, p. 206 p. 207 p. 208 l. 4-7]. These technologies differ in data requirements, functional specification, structure, and nature of results.

Each candidate technology is inadequate to bridge the discontinuity indicated in Section 1.1:

1. Tables cannot be effectively constructed for combinations of multiple symptoms, and fail when required symptoms have not been entered (see Definition 3.20). The contents required for such tables require knowledge that is not available.
2. Smart systems do not represent a specific technology (see Definition 3.15) and a wide variety of suggestions appear in the author of the `105 patent’s deposition and expert testimony by others. We deal with that issue in Section 1.5 below.
3. Expert Systems, defined in the materials as using Rule-based technology (see Definitions 3.17 and 3.19) could not cope with the complexity of the required medical reasoning at the time the patent was granted - and still can not do so.(see Section 1.6 and our review of the state of the art (Section 4.6) , Kaliski review at 5.5).
4. Factor analysis over the entire domain of medicine requires data volumes that exceed globally available resources (see Definition 3.21) Cummings can only provide some generalities, although he admits that is difficult and risky:

> Q: Okay. How do you actually take symptoms and come up with a proposed mode of treatment? How is that actually done?
> A: Through pattern analysis.
> Q: How is pattern analysis done?
> A: Basically, when you have the outcomes from an experience of employees (sic) and you are able to factor-analyze what are the best outcomes for treating various conditions.
> Q: And you knew about pattern analysis when you filed the application?
> A: Pattern analysis?
> Q. Yes. A: It is a statistical concept. [Cummings II:2000, p. 206 l. 3-16].

His experience was limited, and even in about 1996 had not progressed beyond the scope of a Health Risk Advice system.

> "HRA has somewhere over 40 variables." [Cummings III: p. 344] while symptoms encodings number over 8000. (see Definition 3.1)

Any computing technology needs input in order to generate results. Nowhere in the patent are their interfaces defined, other than by arrows in the Figures, indicating communication lines. As described in Section 5.5.1 of this report, Kaliski uses his expertise to fill in technological gaps without addressing the problems presented in the discontinuity defined in Section 1.1. The design, engineering, and construction of the required technologies and their interfaces would be a feat requiring more than the ordinary skill and could not be accomplished without undue experimentation and true inventiveness. As the `105 patent is described, these technologies are in conflict with each other.

Filling the gaps with manual processing, specifically physicians diagnosing patients in their offices and medical directors at an insurance company performing adjudication of claims, is an arbitrary and inappropriate extrapolation (see Section 1.1.2).

1.3 Utilization Review

Utilization Review is a means to assure quality of care. The patent specification and the claims use the term inconsistently. That inconsistency fatally effects the reports and depositions presented by the plaintiff. We provide the commonly agreed upon definition in Section 3.9 below. We use the term cost-effectiveness review for the task of identifying treatments that have costs that are not warranted by the medical benefits they provide, see Definition 3.10. Singer confirms that distinction [Singer:2000D, p. 15], see also Section 5.4.

In the specification of the `105 patent [`105: c. 1 l. 41-42], `utilization review' is shown as an example of obtaining second opinions. That appears to be erroneous. In the summary of the specification of the `105 patent [`105: c. 1 l. 57], a `utilization reviewer' seems to be equated with a case manager (see Definition of Second Opinion in Section 3.6).

The use of `utilization review' in the object and function section of the specification of the `105 patent [`105: c. 2 l. 15-18] implies the traditional usage (See Definition 3.9) since recommendations include both treatments to be given and to be avoided for certain diagnoses. In the same section [`105: c. 2 l. 28-34] inappropriate utilization, presumably as defined 3 sentences earlier, is to be facilitated by a `smart system'.

However, as used in Claims 1 (and its dependent Claims 2 and 3), 4 (and its dependent claims 5, 7-12), 47 (and its dependent Claims 48-51), 50, 55, 97 (and its dependent Claims 98-101), and 102, the term `utilization review' only refers to denial of reimbursement, and hence only performs cost-effectiveness review. In Claims 50 and 51, obtaining a second opinion is included in the utilization review. Since a committee normally carries out utilization review, the implication that the claims refer to cost-effectiveness review, as we define it, is further strengthened.

In reference to the claim construction, this confusion is exacerbated. Allcare cites a definition of `utilization review' that is close to the traditional meaning, i.e., our Definition 3.9, while TRIGON, as an insurance carrier, defines `Utilization review' in sense of cost-effectiveness review (our Definition 3.10). However, when Allcare argues infringement by TRIGON, it appears that they too, use the concept as defined by us as cost-effectiveness review.

This inconsistency has effected the depositions taken. While the author of the `105 patent, Cummings considers that utilization reviews exist to improve health care quality, he has made mixed statements:

> ... the patent application basically points out there are payment systems out there and there were magnetic payment systems and those kinds of things happening in the world, and really the significance of the patent was that it integrated the totality and especially added the whole utilization management, utilization review, second opinion, all the medical management components, where largely all we had was financial management [Cummings:2002, p.85 l. 8-16].

versus

> "Q: so the payer, typically, sets the rules for the predetermined procedures requiring utilization review
> A: Right" [Cummings I :2000 p.163 l .14-15].

Many of the Allcare experts, when supporting infringement, use the term in the limited sense of Cost-effectiveness Review. For instance, Holland, having focused on financial controls for much of his professional life, frequently uses the term `Utilization Management' when Claims Reimbursement Cost-effectiveness Review is intended [Holland:2002, pp.35-38, 66-76]. On page [Holland:2002, p. 152], it becomes clear that the focus of the `smart system' aspects of the claim and the needs for `utilization management' differ. [Singer:2000D, pp.59-61 distinguishes getting pre-authorization and utilization review, but when comparing the ‘105 patent to the services provided by OptiMed refers to that process as utilization review [idid, pp. 81-83].

There is no trustworthy basis for the applicability of the patent because of the inconsistencies in the use of the term utilization review.

1.4 Medical History.

The medical history is the major element of the patient's chart (see Definition 3.7). One of Allcare's experts agree that the `105 system needs a reasonably complete record of the patient's medical and insurance history [Singer:2000], see Section 5.4. The named author of the `105 patent of the patent describes in his deposition the many elements that were available in the chart at his hospital in 1990 [Cummings I:2000, pp. 82-84]. The term `Medical History' does not appear in the specification, but frequently in the claims of the `105 patent. It is unclear in the `105 patent what the `Medical History' contains, where its

contents originates and how its contents is entered. We are hence forced to infer guidance indirectly, using the figures, the claims, common references, and the expected knowledge of a `person familiar with the art'. Unfortunately, the results are inconsistent, particularly in light of Allcare's insistence that a Reimbursement Claims History (see Definition 3.8) is a Medical History.

Figure 1 shows a Physician File (44) and a Claims File (20). Figure 3 shows a Physician File attached to the Physician's Office Microcomputer. In Figures 5, 6, and 7 various patient visit processes take place that are based in the physician's office, including accessing the patient's chart/record (105 in Fig.5). We hence see that the medical history is accessed at the Physician's office microcomputer. The `105 patent "contemplate(s) the physical location of such data in other sites as well as, or in addition to, files at the physician's location." ['105: c. 6 l. 51-54]. Note that access to the full physician chart by insurance companies is inappropriate. Selected items that may be accessed by insurance companies for a limited time are shown in [MIB:2002]. An HMO, being a provider of healthcare, may keep such data, but should not reveal them to an insurance company unless needed for adjudication of a specific reimbursement claim.

In the `105 patent, reimbursement claims are transmitted to a central computer (200 of Fig. 8) and presumably stored in the Claims File (20 of Fig.1). "There is stored detailed information covering relevant items of interest in ensuring accurate administration of claims in accordance with applicable criteria." [`105: c. 5 l. 3-6], as defined in (see Definition. 3.8). Claim adjudication and reimbursement follow. These are activities particular to an insurance carrier or its service organization.

The actual `105 claims use the term `Predetermined Items of Medical History'. A physician's chart should not be constrained to predetermined items, since patients present a broad variety of symptoms and diseases. This wording makes it likely that a reimbursement claims history is intended.

a. In Claims 4 and its dependent Claims 5, 7-12, Claim 19 and its dependent Claims 20, 22-27, Claim 31, Claim 57 (dependent on Claim 55) and its dependent Claims 62 and 63 (in turn dependent on Claim 55), Claim 70 and its dependent claims 72-81, Claims 82, 83,84, the processes include determination of appropriateness of payment and are hence based in the insurance company, implying that the term refers to Reimbursement Claims data and possibly other permitted data, although it is never stated where any other data might be obtained.

b. Claim 47 and its dependent Claims 48-51, and Claim 97 and its dependent Claims 98-101 require utilization review (see Definition. 3.9) and hence outside access is required. Here we have an interaction with the inconsistency of the term `Utilization Review' in patent `105 (see Section 1.3). If the meaning is according to the accepted medical definition (see Definition 3.9), then the outside access is by an institutional review board that has legitimate access to the full chart (see Definition 3.7) If the meaning is the restricted meaning often

implied in the `105 patent, namely cost-effectiveness review performed at an insurance company (see Definition 3.10), then only access to the Claims History should be provided.

c. In Claims 32, Claim 34 and its dependent Claims 35, 37-46, Claim 82, Claim 83, Claim 84, Claim 85 and its dependent Claims 86-94, the operation can be performed within the Physician's office, and hence can refer to a true `Medical History'.

d. In Claims 5, 20, 35, 71, 86 and 97(c) `Physical Profiles' are made available as part of the Medical History. Since Physical Profiles should not be made routinely available to an insurance carrier, they should not appear in Reimbursement Claims History (see Definition 3.8). However, Claims 5 and 20 depend on claims that involve reimbursement, and hence imply that a claims history is intended when the term `Medical History' is used.

e. Claim 97 already has the inconsistency due to the term `Utilization Review'. The use of `Physical Profile' in Claims 35 and 86 strengthens the assumption that a true Medical History (Definition 3.7) is intended for Claim 34 and its dependent Claims 35, 37-46, as well as for Claim 85 and its dependent Claims 86-94.

f. For most of the tasks to be accomplished in the various claims of the `105 patent, a comprehensive medical history, (as defined in Definition3.7), is essential. A patient would not want to receive advice from a physician regarding "mode of treatment") based on a Reimbursement Claims History as proposed in (Claims 1,2, 4 and its dependent Claims 5, 7-12, Claim16 and its dependent Claims 17 and 18, Claim 19 and its dependent Claims 20, 22-27, Claim 34 and its dependent Claims 35, 37-46, Claim 52 and Claim 55 and its dependent Claims 56 to 66, specifically Claims 65 and 66, Claim 67 and its dependent Claims 68 and 69, Claim 70 and its dependent Claims 72-81, and Claim 85 and its dependent Claims 86-94).

g. Neither would patients want to have "ancillary services", including their medications being prescribed based on a Reimbursement Claims History (Claim 2, Claim 17, Claim 34 and its dependent Claims 35, 37-46, Claim 47 and its dependent Claims 48-51, Claim 53, Claim 68, Claim 85 and Claim 97 and its dependent Claims 98-101).

h. It would be equally unwise to direct a patient's "preventive health routines for addressing each of any identified plurality of potentially health-destructive conditions including excessive weight, high blood pressure, smoking, and insufficient exercises "based on a Reimbursement Claims History (Claim 3, Claim 18, Claim 41, Claim 47 and its dependent Claims 48-51, Claim 54, Claim 69, Claim 91, and Claim 95).

The effect of the inconsistencies a. to h. above is that an interpretation of the term `Medical History', and the legitimate and actual contents of a `Medical History Data Bank' will differ depending on which claim is being asserted and defended. We find such confusion intolerable. It results in inconsistent interpretations and, therefore, the claim term is not susceptible of definite construction. In addition, Allcare's urged construction is simply arbitrary. Plainly, the claims do not provide sufficient notice to permit one of ordinary skill in the art to ascertain what is within and without the scope of the claims. It also disables any reliable guidance towards implementation by anyone, experts or mere programmers. Notwithstanding this, points e, f, g and h make it clear that use of a patient Chart rather than a Reimbursement Claims History is a more appropriate interpretation of Medical History.

We also analyzed the data flow for the contents of the `Medical History' as described in the processes of the claims. Instead of obtaining clarification, the specification revealed more discontinuity.

a. In Claim 4 and its dependent claims 5, 7-12, Claim 19 and its dependent claims 20, 22-27, Claim 34 and its dependent claims 35, 37-46, Claim 70 and its dependent claims 72-81, claims 82, 83,84, Claim 85 and its dependent Claims 86, 91-96, and Claim 97 and its dependent claims 98-101, there exists a databank for medical history without a means for entering data and retrieving results. The data being entered either from a card or manually in Claims 11, 12, 26, 27, 92 and 93 would not comprise a medical history. The data entered in Claims 7, 22, 37 are restricted to patient identification. The data being entered in Claims 94, 95,and 96 are not patient-specific and hence cannot serve a medical history.

b. Claims 6, 21, and 71 do specify an input terminal for medical history, clearly showing that an input means is needed unless only legacy historical information is to be stored.

c. In Claims 72 and its dependent 77 and 78, the medical history is being accessed. Here only legacy historical data are available as part of the medical history. This observation is made as well by [Kaliski:2002, p. 47], (see Section 5.3.2). Past information alone is clearly inadequate for making current decisions about requested patient treatments.

d. In all other claims of the `105 patent, the potentially costly existence of a historical medical history database is merely for beauty and comprehensiveness, since data is neither entered nor taken out.

This patent obviously does not provide adequate guidance to anyone steeped in the art of construction of health care systems to implement consistently the important medical record component and its functions that appears in the majority of the claims of the `105 patent. This becomes obvious in [Holland:2002] discussion, see Section 5.6.1. The resulting systems would differ a great deal. It does provide an opportunity for experts to improperly read their experience into the intent of the `105 patent. The efforts by Allcare

to assert the theories of infringement are based on an interpretation of the language that is inconsistent with many of the claims and, as such, is arbitrary and not supportable.

1.5 Smart Systems

The concept of `Smart Systems' appears several times in the figures and specification of the `105 patent but is not further defined. For the systems and methods according to the claims to be operative, such ‘smart systems' are needed to bridge the gap shown in Section 1.1. Even the plaintiff's expert reports recognize that their abilities are essential to the validity of the patent [Kaliski:2002], (see Section 5.5.3). Since there is no consistency to their requirements, also recognized by [Kaliski:2002], we address each of these occurrences one by one, before summarizing our understanding.

1. Figure 1, label 21: Smart system, drugs, and diagnostics: is explained in Column 5, line 10: Cylinder 21: smart system (diagnosis and drugs) does not state what is being accomplished, only that it is "contemplated by several of the following operations including ... "Utilization Review/Second Opinion/Procedure Approval". Since the diagnosis is an input parameter, we must conclude that having a `smart system' facilitates reviewing prescribed drugs during Utilization Review. I could not locate the promised "ensuing description" which made this portion of the system "very versatile", since this is the only occurrence of the term "versatile" in the `105 patent.
2. Figure 5, the transition from the box labeled 111 "Input reason for visit and tests ordered" to box 112 "Access Patterns of treatment Protocols" requires a smart system, as stated in [Cummings:2000, pp. 161-162] "In accordance with the smart system characteristics of the invention, physician file 44 preferably will include an identification of the most commonly encountered diseases and other ailments, together with symptoms usually associated therein. Accordingly, if symptoms are entered into the terminal, an identification of the corresponding illness and so forth that are most likely to that medical condition and recommended treatment" Q: so the system of Claim 1 is a smart system, correct?" [Cummings I :2000, page 161]: "Right".
3. Column 2, line 34: As the second basic (non-optional) feature "The invention" provides an "integrated service [..] thus reducing time, direct cost, and indirect cost often incurred through duplication of tests, excessive paperwork and inappropriate utilization, thus enhancing the ability of the system to provide quality health care through case management and physician interaction via smart system". These services are broad, and recognizing inappropriate utilization is indeed a task requiring smarts. This task could well be termed `utilization review', but that would then not be based in a specific physician's office. Case management is not defined either.
4. Column 5, line 10: "Figure 1 reveals the inclusion of a smart system 21 including parameters dealing with diagnosis and drugs (as hereafter described)". The figure depicts a file or databank, although the smart system is described as being a processing system. Later references to drugs are limited to wellness management and drug profile reporting. The claims never mention drugs in either sense, but

we could assume that treatments, medical history, and ancillary services may have components including prescribed drugs. The lack of precision allows a variety of inferences about the `105 patent's intent, disabling a definite implementation.

5. Column 6, lines 55-70: "In accordance with the 'Smart System' characteristics of the invention, Physician File 44 preferably will include an identification of the most commonly encountered diseases and other ailments, together with symptoms usually associated therewith [Smart System (3)]. Accordingly, if symptoms are entered into the system terminal (e.g., one of terminals 11a-11c), and an identification of the corresponding illness is requested from the Processing System 10, the physician's file is interrogated, and the system prepares a list of the most likely medical condition corresponding to such symptoms, together with the generally approved and/or recommended treatment protocols. It also contemplates the identification within Physician File 44 of those procedures for which Utilization Review (see Definition 3.9) and/or Second Opinion 34 (see Definition 3.6) are deemed necessary or desirable. "
6. Column 9, lines 53-65 (describing rectangle 110): "By this is contemplated the entry of symptoms and other data which can assist in making a diagnosis and identifying the aforementioned recommended treatment protocols. Thus, the physician is assisted in correlating the observed patient symptoms and test results so as to identify the most likely causes of the health problem, complete his diagnosis, and prescribe the most appropriate treatment protocols." This `smart system' instance describes concepts that were under research and development at the time (see for instance Section 4.6.2 - the Internist system). Today some software tools are available to practicing physicians (for example see Section 4.6.7 on Ovid), but not in the integrated form contemplated in the vision presented. They typically address sub-problems, i.e., cases where the physician has made at least a preliminary diagnosis and wishes to refine it, or get a list of treatment choices, perhaps with statistics of the cost and success of these choices on similar patient populations.

   All references in the `105 patent refer to the smart system being available to the physician at his or her office. Any assertion made by the plaintiffs that the `105 patent also intended to cover services at an insurance company is an extrapolation. We know of no systems that infer diagnoses or treatment from symptoms that are connected to Claims Reimbursement Systems.
7. The functions allocated to smart systems in points 1-6 above relate to what is referred to as an `expert system' in Fig.6 of the `105 patent. See Section 1.6 for an analysis of that concept.

The patent does not explicitly claim ‘smart systems’ as an element. It does include means plus function limitations whose functions require such ‘smart systems.’ The referenced ‘smart system’ is provided in order to miraculously solve problems that conventional, algorithmic (see Definition 3.16) computing can not solve. Integration of smart concepts into the real world has always been the vision of the many competent people who actually researched, developed, and invented precursors to ‘smart systems’ intended to perform as described in the ‘105 patent. No one, including the ‘105 patent,

has described the structure of such a system in a manner sufficient to permit one of ordinary skill in the art to make and use such a system in a practical health care setting.

1.6 Expert System.

Figure 6, rectangle 123 shows "An Expert System that compares Diagnostic Testline Attendance Based on Physician Goal and Patient History". The related text at col.2, lines 18-34 explains:

> In addition to the foregoing, the System also includes provision for further diagnostic support. This is indicated by rectangle 122 `Is diagnostic Suport (sic) Needed'.

If the answer is "No", then the system continues on as indicated. However, if the answer is "Yes", then the system invokes such additional assistance as indicated by rectangle 123 "An Expert System that Compares Diagnostic Testline Attendance Based on Physician goal and Patient History." Thus, the physician is able to determine the testing options based on conditions and the condition of the body that each test was designed to report on. In addition, the physician is given the cost of each testing procedure, including those that are laboratory or radiology based. If requested, the system will allow the physician to select through a "triage process to determine what test would yield the best data for diagnosis of the presenting problem."

We provide the commonly accepted definition of `Expert System' in Section 3.17 and note that `Expert Systems' are considered to be a specific type of `smart system`, as used in the context of this patent. Unfortunately, here we cannot understand what the system does. We are at a loss to understand the term "testline". It does not appear in our medical dictionaries or in the 20-volume set of [OED:2002]. The associated text does not help much, and various people `familiar with the art' would arrive at differing conclusions, if any, about what is intended here. The term `triage' is misused here as well. Triage means selecting from a set of patients those that (1) can benefit from treatment, and ignoring those (2) too ill to benefit from scarce resources and those (3) well enough to survive by themselves.

We are also not informed about the expert technology to be used here. In his deposition [Cummings I :2000, p.161], see Sect.5.1, he refers to an expert system as being an artificial intelligence system that is both rule-based and can learn. We do not know of any rule-based system that can learn, although systems that can learn comprise the holy grail of artificial intelligence.

This is the only place where the term `expert system' is used in `105. It does not appear in the claims. Given the vagueness and the author of the `105 patent's poor understanding shown in the deposition, we conclude that the use of the term `expert system' in the patent was due to its attractiveness in marketing and is not a valid technical specification.

1.7 Lack of Originality in Composition

The specification, as the author of the `105 patent himself has stated [Cummings 2002, p.69 l. 1-4, p. 128 l. 20-25] represents a vision of a comprehensive health care system. All of the many features described in the specification of the `105 patent had been available in a variety of systems. We refer to the prior art summaries in Section 4.3,4.4,4.5, and 4.6.

The actual claims of `105 focus on a subset, namely Healthcare Reimbursement System. The specification is not coordinated with the claims of the '105 patent.

We address in this section the features cited in the specification. We address each feature distinctly. We also note that all of the features that are mentioned in the claims have had examples in prior art. The compositions presented do not express originality, they are samples selected from a menu of choices, and often not even consistently (see Section 1.4, Medical History, for instance)

	Feature in specification	**claim**	**USC** [Brian:1981]	**AAMRS** [Wiederhold: 1975]	**Next Three Generations of Healthcare Information Systems** [Halverson:1984]	**precursors**
1	integrated wellness	missing	dietary, discharge care plans	yes	yes, "from womb to tomb"	Kaiser
1a	integrated service via a smart system	missing	integrated, patient diagnosis and order profile	integrated medical and financial	yes, AI, expert sytems	OncoCyn
2	customized wellness re-commendations	3,18, 41, 47,54,69, 91,97	dietary, discharge care plans,	yes	yes, "from womb to tomb"	Kaiser, Regenstrief
3	group health management	82,83	discharge care plans with patient chart	could be, follow ups combined with patient chart	yes, analyze health care protocols to determine standards and norms	Kaiser, HCHP @ MGH
4	integration of in- and outpatient records	missing	yes	yes	yes	Kaiser, MGH
5	inclusion of ancillary services	2,17,34, 47,53,68, 85,97	yes	yes	yes	TDS, HCHP, ARAMIS

Table 1.7 Features of the `105 Patent Specification and Their Anticipation

	Feature	**claim**	**USC** [	**AAMRS**	**Next 3 Gen's of HIS**	**precursors**
6	workman's compensation capability	33, 84	medicare, insurance billing	multiple insurance carriers	yes, includes standard insurance	Technekron
7	precertification	9,10,24, 35,40, 47-51,60, 61,75,76, 89	utilization review, reports, treatment plans, admission and transfers (ADT)	referrals, follow-ups, triage, cost reviews, utilization reviews, admission and transfers	integrated financial and patient management with clinical decision support systems	Optimed
8	patient discharge planning and monitoring	missing	discharge care plans	follow ups, patient chart, discharge and transfers	integrated financial and patient management with clinical decision support systems	Help, oncocyn
9	interactive links to cost-benefit review	1,9,47,48, 52,55,97,9 8	yes	yes	integrated financial and patient management with clinical decision support systems	OptiMed
9a	second opinions	73-76	utilization re view, treatment plans, ADT	as a form of cost reviews and utilization review, ADT	integrated financial and patient management with clinical decision support systems	BankOne
10	customized utili-zation review per criteria	ignored since neither the specifications nor the claims defined what customization is intended.				
11	concurrent and retrospective review	1,4,16,19, 52,55,102	utilization review, reports, treatment plans	yes	integrated financial and patient management with clinical decision support systems	OptiMed, Lifecard
12	quality control by cost-benefit review	47, 97	yes	yes	integrated financial and patient management with clinical decision support systems based on medical expert systems	Optimed
13	on-line test results, images, in MD offices	missing	yes	yes	yes	Oncocyn
14	real-time connection to employers	missing	no	no	no	VA
14a	payroll linkage	31,37,47,8 2, 83,97	no	no	no	Technekron
15	banks are inte-grated for EFT	missing	yes	yes	yes, enhance financial	BankOne

Table 1.7 Features of the `105 patent Specification and Their Anticipation, Continued

Reimbursement systems existed prior to the filing of the patent. (see [BankOne:1989], and Singer's correspondence [Singer: 2000D, Exhibit 17]).

[Singer:2000]) rejects certain prior systems as not being comprehensive. However, the prior art addressed by [Singer:2000] operated in association with other subsystems serving other aspects of healthcare, even if not in the most elegant fashion.

The ‘105 patent discloses a tight integration (see Definition 3.22) of information flow to support all health care functions: We quote from the patent [`105: c. l. 36-51]:

> However, such systems have not heretofore featured the total health care function, for they have not integrated important elements of total health care such as comprehensive preventive health measures, the review of the necessity for implementing selected procedures including changes in life styles, the obtaining of second opinions, (i.e., utilization review/case management) and other functions contemplated by total health management such as ancillary services. Neither have they included integration of the active participation by a patient's employer or inclusion of a patients' own available cash balances. Accordingly, since these missing functions are important ingredients to extend proposals of the prior art to fully comprehensive medical care, there has continued to be a need for a system which provides full integration of each of the aforementioned activities.

In his deposition, Cummings reinforces that various independent systems must operate together [Cummings:2002, p. 8 l. 14-16, p. 9 l. 12 to 25, p. 10 l. 1-10]

> Q: What system is that that you use?
> A. We use a variety of systems, so they're integrated together, but our major clinical system is SMS."
> Q: What other kinds of systems are involved?
> A. There's lab systems such as SunQuest systems. There's picture archiving systems for Pac's applications. That would be in the area of radiology.
> Q. Anything else you can think of?
> A. Not -- I mean, there's a whole mapping of all those systems. There are a number of them.
> Q. Do those systems interconnect with each other in any way?
> A. Yes. Not to the degree we would like to have them interconnect, but some of them do -- you know, they report information, and we are integrating those all the time. That's the Quest.
> Q. Now, these three examples that you gave me, are they part of the SMS? Are they separate from the SMS?
> A. SMS is the one around the clinical, the nursing and the nursing clinical and those kinds of things. The SunQuest system or the lab system would be a system they can interface with.
> Q. Okay. They also interface with a picture archiving system?
> A. Yes, they do theoretically. How well that's deployed or how well that executes, we're in the process of implementation, so stay tuned.

It is an open question to what extent the systems have to be tightly integrated, i.e., supplied by a single vendor, as the quoted prior art has been, or composed, as we find in the practice at the author of the `105 patent's home institution, at the accused sites, and as

is and has been a practice in the industry since before the filing of the ‘105 patent. No definition is given, and the practice of computing has not been consistent. The early dictionaries define

> "Integration: The combining of diverse elements of hardware and software, often acquired from different vendors, into a unified system"; [Webster:1994],

but later editions give up and fail to define this or related terms [Websters:2000].

The `105 specifications also state:

> Thus, as earlier mentioned and as described below, supporting and ancillary services are integrated into the System and are effective to provide such ancillary services and support as are called for by the attending physician or other authorized staff personnel.

Here it appears that other systems may be integrated with the system described in the `105 patent. No further use of the term is made, except that the preambles to Claims 47-51 and 98-101 state that these claims represent integrated systems. We could not find a structural difference between these nine systems and the 92 other system configurations. We must conclude that the labeling of systems as being `integrated' or not within the scope of the `105 systems is meaningless.

Given this lack of guidance from the `105 patent and the relevant literature, we conclude that the patent can not restrict nor demand that systems be constructed as a whole, versus being assembled from components.

In table 1.7 we match the features listed in the specification with prior art in individual systems. We find that all of them have existed in prior art, and that all of them, except smart systems, have been included as components in larger healthcare systems.

The novelty, if any, set forth in the claims of the ‘105 patent is the addition of a `smart system', as described above in Section 1.5 to perform the function of tentatively identifying a proposed mode of treatment in response to input of data symbolic of symptoms. Note that this capability recapitulates the issue in Section 1.1 of this report, namely that there is a "discontinuity". The `smart system', needed to distinguish the `105 patent from common understanding and practice, is not described except by use of the term itself in the patent specification. It plays an important role in the depositions of the author of the `105 patent [Cummings:2000].

1.8 Obviousness

As described above, the features described in the `105 patent have been available individuality or in various combinations in earlier systems. Combining them in a modular fashion would have been obvious to one of ordinary skill in the art at the time of the filing of the ‘105 patent. The list of over 175 features of HIS, given in [Wiederhold:1981] and [Brian:1981] are prefixed with the advice:

> The matrices are intended to serve as points of reference for hospital decision-makers to use in the process of developing system specifications and selecting an AHIS. The Hospital/Applications Matrix may be used to identify what types of applications are being employed by various sizes of hospitals. The System Supplier/Application matrix may be used to match against your hospital's desired application profile to determine the likelihood that the configuration desired will be available from one or more potential suppliers [AHIS:1981, p. B2].

For users of the Automated Hospital Information Systems Workbook [AHIS:1981] the choice of which sub-systems to integrate is a cost-benefit tradeoff and does not involve any new great intellectual insight.

> Technical elements of the descriptions include a listing of the applications offered and their mode of operation, the type of user interface equipment used, data retention characteristics and development support requirements. These elements are designed to be employed by personnel with the technical experience and expertise to determine the relevance of these characteristics to the individual hospital's desires and requirements [AHIS:1981, p. C1].

That various combinations of these features will be available in actual systems is made clear in the literature. See Section 4.3.2 and 4.3.3.

Being comprehensive, (i.e., including all features), is an abstract ideal in health care. The software is already costly to implement and maintain. But the cost of the software is a small fraction of the cost of operating a health care system. Data, as patient's symptoms, medical history, diagnoses, physician's and nurse’s notes, treatment records, etc., are voluminous and costly to collect and record accurately. A designer of a health care system will weigh the costs versus the benefits to be obtained. Even promoters of “comprehensive” healthcare systems have stressed the need to proceed gradually, starting with a few modules and adding other modules as needs arise and justify the additional cost [Barnett:1967] [Barnett:1976] [Barnett:1978] [Barnett:1987]. Selecting modules incrementally, as the need for sharing the knowledge that is the basis for the systems arises, is also emphasized in Greenes [Greenes:1990].

Since the specification considers all features to be optional, the number of distinct `Comprehensive Health Care Systems' covered is huge (well over a million). Since all of the features were preexisting [Cummings V:2000, p. 203 l. 17-25] except for the augmentation with a `smart system', investigation of prior art not including a `smart system', would have required more resources than the patent office could possibly bring to bear on the issuance of the patent. Many preexisting systems contained several of the 18 features, but none provided the automated diagnosis function. We deduce hence, that the inclusion of a ‘smart system’ that tentatively identifies a proposed mode of treatment in response to input of data symbolic of symptoms is indeed the distinguishing feature of the ‘105 claims.

The fact that the inclusion of features is not one of invention but merely one of selection is clear from the claims section of the patent itself, where claim 4 and its dependent

claims 5-12, claim 19 and its dependent claims 20-27, claim 34 and its dependent claims 35-46, claim 70 and its dependent claims 72-81, claim 85 and its dependent claims 86-96, and claim 97 and its dependent claims 98-101, all show a similar structure, as if they were mechanically generated. The intellectual contribution of permuting claims is low, and does not reflect inventiveness, but only a desire to profit from the work of others.

1.9 Vagueness in the Patent

In addition to the crucial discontinuity cited in Section 1.1, there are many other instances of vagueness in the patent, that deny the public of reliable notice of what is within and without the scope of the claims. We listed specifically the problems with Utilization Review (Section 1.3), Medical History (Section 1.4), smart systems (Section 1.5), and Expert Systems (Section 1.6). There are further instances of vagueness that we address below.

1.9.1 Comprehensive is a term both applied to the computer systems and health care services. We provide definitions of both in Definition 3.12 and 3.13. Both of them have unattainable, ideal endpoints.

The comprehensiveness of health care computer systems is limited by our ability to build, obtain data, maintain, and pay for them. For each candidate feature (see list of `105 features in Section 1.7) a cost/benefit analysis is required to see if there is a payoff.

The comprehensiveness of health care, providing quality healthcare for everyone throughout their life is an even loftier goal, and impacts our national economy and political will. It can be aided, but not achieved by having better systems.

Unfortunately, throughout the patent and the ensuing reports the two are not well distinguished, leading to confusion and inconsistencies, see Section 5.5 and Section 5.6. The confusion gets worse when the term comprehensive is applied to health care payment systems, as implemented by TRIGON. (see Section 5.8).

1.9.2 Integrated System: The term, integrated system, is used a few times in the specification and in the preambles of 10 of the claims, but is never defined. In general, integration is a desirable goal, but the means to achieve it vary greatly. Tight integration typically means a fixed set of services provided by a single vendor. Loose integration allows multiple subsystems to inter-operate asynchronously, initiating remote processing and communicating data electronically as needed. Since it does not have a fixed meaning in the literature [Webster:1994] versus [Webster:2000] it has led to misleading arguments as to what the intent of the patent is and what prior art is relevant. We cover the issue in more detail in Section 5.4.2 where such an argument arises.

1.9.3 Versatile: It is stated that "the System is very versatile in that it can be tailored to include either or both of the Utilization Review and Second Opinion" (6, 20-22). How this versatility is achieved is not stated. Having choices in implementing software systems is common. It is unclear if `very versatile' means a simple choice in system

feature selection or something that is really uncommon. This appears to be merely a marketing term of no technical value, although it is cited as a benefit in some expert reports.

1.9.4 Role of the Patient. We recapitulate an observation of [Kaliski:2002, p. 9, footnote 3] "In fact, although perhaps desirable, nowhere in Figure 1 of the `105 patent is the patient even depicted as a participant (unlike, for example, a financial institution), although the specification plainly states that Fig. 1 'depicts the principal components of the preferred system in accordance with the principles of the invention.' (4:5-7)" The importance of the patient as a participant is emphasized in the abstract and a few times in the initial specifications. Subsequently, the patient is reduced to a supplier of symptoms and provider of insurance or payroll deductions. The only automated participation of patients is the access to their available cash balances (1:46). Marketing of comprehensiveness and neglect in execution is known to create unhappiness with the consumers of healthcare services, and will also create problems in any system validation.

1.9.5 Patient Data Entry. Only Claim 58 specifies entry of individual patient information. However, many of the other claims depend on having such data available,

1.9.6 The Terminal shown is a Point-of-Sale Terminal Phone. The function of the input means is performed by the terminal shown in Figure 2, which is clearly a telephone with the capability of a swipe card and speed dialing. It does not include the capabilities required for the patent and listed in the `105 specification:

> Now turning to FIG. 2, it will be observed that it depicts, in a perspective view, a terminal suitable for utilization in the System as identified by symbols 11a-11c in FIG. 1. Although as mentioned above, all of the features of the illustrated terminal are not required in order to practice the principles of the invention and thus some of them are optional, it is deemed apparent that each of the features illustrated are attractive and add to the usefulness of the terminal.
>
> The terminal of FIG. 2 includes a main housing 50 having a visual display window 51, a card data entry slot 52 having an elongated portion 53 and an enlarged portion 54, conventional manual data entry keyboard 55 and 10-key numeric calculator 56. It also includes conventional telephone handset cradle 57 and telephone handset 58. As will be evident from reference to FIG. 2, the terminal is operative in accordance with techniques well known in the data processing arts. Thus, for example, manual entry of information may be made by depressing the appropriate keys on keyboard 55, and information entry may also be made by inserting a conventional or special data-containing card (e.g., a "swipe card") into data entry slot 52 and moving it laterally there through. Although not necessary to the practice of the invention hereof, it is contemplated that the terminal will be responsive to data entry through conventional credit cards as well as special cards that may be issued for such purpose. It is also contemplated that the terminal may be adapted for reading bar codes such as those conventionally

employed for identifying merchandise.

1.10 Organizational and Syntax Errors

The number of errors in the ‘105 patent is such that interpretation and search are hampered.

First of all, the description of the preferred embodiment occupies most of the specification section. That preferred embodiment lists so many choices that we cannot tell what is actually preferred. It does not indicate any actual implementation, and does not show any demonstration of the system, even in one single version. We are not surprised that Allcare and Cummings have never implemented a system according to the patent [Kurtyka:2002, p 291-292].

There are many important features of health care that appear in the specification as contribution of the invention, but are not specifically claimed. For instance `planning', an important aspect of developing treatment sequences, is mentioned several times in the specification, but never in the claims. No technology for planning is indicated in the `105. patent. Should we now assume that planning is an implied step in any step of any claim where planning makes sense?

Including many substantial unclaimed features is confusing to reviewers, who will tend to ascribe aspects to claim elements that are not actually there. We see in the expert reports for this case that on some topics the discussion focuses on the claims, and on other topics on the specification and the preferred embodiment. Since the specification and the claims do not match, arguments ensue that should not occur.

1.10.1 In the Specification

- "several of the following operations" is not followed by any operations [`105: c. 6 l. 16]
- promise of an "ensuing description", which never occurs [`105: c. 6 l. 20]
- 1-800-4Health - real phone number not associated with Allcare.
- The term "Diagnostic Testline Attendance" [`105: box 123] goes undefined.
- Wellness Health Management System goes undefined.
- Transaction File, Procedure File, and Library file named but not used or defined.

1.10.2 In the Claims

- In Claim 16b, use of 'option' instead of 'opinion'.
- Claim 56 is an incomplete sentence.
- Claim 67 clearly shows the direct mapping of symptoms to treatment plan was intended to be an automated process.

  67(e) accessing said data symbolic of patient symptoms for tentatively identifying a proposed mode of treatment and

This wording clarifies that the appropriate interpretation of “for tentatively identifying a proposed mode of treatment” is as an automated function based on symptoms. While no additional function or mechanism is described that would enhance the system in this claim, the use of the term accessing at least implies that the data symbolic of patient symptoms has been previously stored so that it could be accessed. Whether or not the system requires prior storage of symptoms does not alter the conclusion that the system automatically generates the proposed mode of treatment and is not a function performed manually by the provider.

- In Claim 85 the proposed mode of treatment is based only on the medical history. We have first an ambiguity of what is intended here (see Definition 3.7). Even if the most liberal definition of Medical History were employed it would be unwise not to consider the problem that the patient is currently presenting.

  1. If the `data bank memory' is at the physician's office then it might contain a proper medical history, but now the `smart system' proposing treatments and ancillary services resides in the physician’s offices. There is no interaction with any insurance carrier.

  2. If the `data bank memory' is part of the insurance carrier's system then its contents are limited to the reimbursed claims history (see Definition 3.8). Any claim history that may be held by a carrier would be insufficient to permit a system to propose a mode of treatment.

  Then procedures are selected before treatments are proposed. There is nothing said about payment.

1.11 Human Intervention for Certain Processing Steps

All of the patents cited in the ‘105 patent have one basic flaw that is from input to automated computation to output. There is no manual human-based step in the automated computational phase. A human may generate input and receive output, but a human does not get involved in the automated computational step.

A work flow system is an example of a mix of automated computational and human-manual intervention. Work is routed in an automated fashion and processed until it lands on the desktop (or email box) of a human. The human reads the work items, performs some actions, marks the work item as completed, and then the work item again enters the automated computational system.

Claims processing when it was all paper based is an example of a 100% human-manual process. As computers evolved and claims systems were built, more of the claims system got automated, but even today there are a work force of humans that look at the claims (CHIPS and TRIMED people for example). It is very important to note that TRIGON

uses a claims workflow system with a combination of automated computational and human-based manual processing.

If one allows a human-based manual step in the automated computation then every system must be allowed, because the human could do anything including another computation.

Both Cummings and Kaliski in their deposition describe systems that are both automated computational and human-based manual processing. The `105 patent in the claims only includes automated computations. The specification talks about both. Their process descriptions swap `smart systems' in and out at will.

Thus, if we follow the structure and operation of the claims section of the ‘105 patent, the recited embodiment is not enabled and cannot be built. If the urged construction, permitting an undefined mix of automated computational and human-based manual processing, is adopted, then there is no distinction between the claimed embodiments and principally manual operations of any other claim processing system, even one that was 100% paper and human-manual. Because the manual versus automated implementation as urged by Allcare is arbitrary, not based on any distinctions described in the specification, the necessary result of adoption of the construction urged by Allcare, Kaliski and Holland is that any system, including pre-1990 Trigon system, would then invalidate the patent.

We do not agree with [Kaliski:2002, [Kaliski:2002D] or [Cummings:2002, pp. 23-25] that all computer programs are smart, as that interpretation renders the term “smart” meaningless.

We also dispute that a proper construction of the ‘105 claims can allow the substitution of automated, computer-based processing by manual handling of medical or auxiliary staff [Cummings:2000][Cummings:2002].

> Q: You envisioned that the invention would require a patient, a healthcare provider, a bank or other financial institution, an insurance company, a utilization reviewer, and an employer?
> A: Yes . . It can also work with paper, a debit card, manually. ...
> Q: So if were all done on paper that would be within the scope of your invention?
> A: Right. Near time is required.
> Q: `Your invention does not cover retrospective systems'.
> A: `It can', [abstract of Cummings II: 2000, pp.130 l. 5 – pp.133 l. 5].

If the claims were to be interpreted that broadly, they would be unsupportable, since mixed (automated and manual) operations have been ongoing for many years in healthcare. Physicians have had to diagnose patients based on presented symptoms since Aesculapius: *Ad sanitatem gradus est novisse morbum* (The first step toward cure is to know what the disease is). Predecessors of TRIGON had to validate eligibility for reimbursement for decades, ever since health care insurance was instituted. [MetropolitianLife:1985]. The prior art revealed in the application for the patent deals

only with automated systems, systems in which there are no intermediary manual processes. We could not locate in the prosecution history any reference to manual processes.

If the '105 claims were interpreted as having a physician converting symptoms to treatment, then the Bank One system shows all of the claimed features, since it expects a physician to make the same conversion, before submitting diagnoses to the insurance system for edit an adjudication [Kurtyka:2002, p 37, 38].

None of the prior art cited in `105 and none of the prosecution history mentions manual steps other than initial input and final payment. The claims do not list intermediate manual steps either, see Section 4.0 for a rationale. If manual conversions were considered by the applicant or the Examiner to be included, prior art showing manual steps would have been cited. That neither the applicant nor the Examiner cited such prior art reinforces our conclusion that proper interpretation of the claims requires automated and not manual conversions.

1.12 The Vision of the Patent Invalidates Subsequent Art

As stated by the author of the `105 patent and many of the experts, the `105 patent presents a vision. Many other people had the same vision and talked about it, often informally at conference keynotes intended to motivate audiences to perform research and development towards the annunciated goal [Barnett:1967] [Barnett:1976] [Barnett:1978] [Barnett:1987] [Halverson:1984]. I quote from my own writings; [Wiederhold:1981, *Databases for Healthcare*]:

> The fact that data are shared promotes consistency of information for decision-making and reduces duplicate data collection, A major benefit of databases in health care is due to the application of information to the management of services and the allocation of resources needed for those services, but communication through the shared information among health care providers, and the validation of medical care hypotheses from observation on patients are also significant.

Patenting the vision of a system that is not described in a manner sufficient to enable one of ordinary skill in the art to make and use the system is a misuse of the patent process. Patenting a non-enabled system discourages research and development in that arena, since the results of subsequent researchers would be covered by the prior patent and hence incur licensing costs, rather than sales or licensing benefits. Hence, in my, non-legal opinion, this patent violates the intent of the Constitution:

> To promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.

because without an enabling disclosure, it does not promote progress.

I am disappointed that the applicant has fallen into the trap of pursuing financial gain based on the ongoing work of others. Instead of helping to improve the healthcare systems, he is forcing the health care industry to defend against this patent, creating costs, distractions, discouragement, and reducing available resources by a high multiple of the financial gains accruing to the holder of the `105 patent.

2. Non-Infringement

The defendants systems differ in many crucial aspects from the systems described in the claims of patent ‘105. The plaintiff and its experts have urged construction and coverage of certain claims of the ‘105 vision that are both unjustifiably broad and vague.

We start by describing elements that occur repeatedly in ‘105 claims that the plaintiff has indicated to be infringed. In Section 2.2, we describe the relevant portions of defendants’ systems. In Section 2.3, we go through all the claims asserted by Allcare versus TRIGON and match the elements that do not fall within the scope of those claims. In Section 2.4, we list individual system components in TRIGON's operation and indicate which of their functions correspond to steps in the `105 claims, and why these TRIGON subsystems individually do not infringe. Finally, in Section 2.5 we briefly cite other issues that substantiate non-infringement.

2.1 Elements that do not read on accused systems

We list now the elements that Allcare has asserted to be within the scope of one or more claims.

2.1.1 No Automatic Denial for Medical Causes

Trigon does not automatically prevent payment for medical reasons.

None of the accused systems prevent or deny payment for treatment automatically for patient-specific medical reasons. Payment will be denied for contractual reasons as specified by the plan, namely, to people that are not members of the plan or for treatments that are specifically excluded in the plan (say psychiatric care). Any further denial of payment is made by Medical staff, i.e., trained MDs.

In [Cummings:2000] the author of the `105 patent tries to generalize the vision of the `105 patent by including manual processing (see Section 5.1.7). Such a generalization would result in a claim interpretation that includes the prior art (see Section 1.2)

The `105 patent, as specified, does not include any structure for manual intervention in the payment approval process. The apparatus description states clearly that all terminal devices, printers, monitors, and displays are located in the physician's office, and the methods described in the `105 claims do not require any such devices to be located at the insurance carrier, inhibiting manual intervention. An expert report [Kaliski:2002] attempts to generalize the specification of the patent by stating that since the `105 patent describes an instance of a distributed system, and since distributed systems have terminals in arbitrary locations, the system described by the `105 patent can have terminals anywhere, including at the insurer's, here at TRIGON's site. This is an unwarranted extrapolation and generalization and is not supported by the specification.

2.1.2 No Automated Processing of Symptoms.

No automated processing of symptoms in the reimbursement claims approval / denial process.

No patient symptom data are available for processing.
Trigon does not process symptoms.
Trigon does not collect patient symptoms.
Trigon does not process symptoms automatically.

In the accused system, approval of inpatient reimbursement claim is based on the contract and the diagnosis of the patient and, if needed, on information obtained by telephonic interaction with medical staff at the hospital. Similarly, in the accused system, approval of payment claim for outpatient office visits and referrals is based on the contract and the diagnosis reported by the physician.

Symptom information is not encoded in reimbursement claims for payment. It could be entered on a text field but is not processed automatically, and not even made available to the medical staff associated with the Trimed system.

The ‘105 patent claims require automated processing based on symptoms.
Trigon does not have more than occasional access to symptoms; those best remain with the physician.
No Trigon systems infringe on that pervasive `105 patent claim in its various forms.

2.1.3 No Automated Processing of the Patient's Medical History.

No automated processing of the patient's medical history in the reimbursement claims approval / denial process.

Trigon's databanks do not include predetermined items of medical history.
Trigon does not store a medical history.
Trigon does not collect predetermined items of medical history.
Trigon does not keep a medical history.
Trigon systems cannot access predetermined items of medical history.
Trigon does not process medical histories.

Trigon's databanks do not include physical profiles.
Trigon does not store physical profiles.
Trigon does not collect physical profiles.

Trigon does not collect a personal health profile.

In the accused system approval of inpatient reimbursement claim is based on the contract and the diagnosis of the patient and, if needed, telephonic interaction with medical staff at

the hospital. Similarly, in the accused system approval of reimbursement claim for office visits and referrals is based on the contract and the diagnosis reported by the physician. Only a limited Reimbursement Claims History (see Definition 3.8) is available to the adjudication process, and even that reimbursement claims history is not available to the automated processes used in TRIGON.

If the Medical Directors (see Definition 3.14) at Trigon need information about the patient's Medical History (see Definition 3.7) in order to help in adjudicating a reimbursement claim, they resort to calling the patient's primary health care provider's office. The patent, in Claims (see Section 1.4) specifies automation in use of a Medical History in reimbursement claims processing, since no Terminal is specified that allows the Medical Director to interact or view a Medical History (see Section 5.5.1). While we could design such a system, and as Kaliski argues (see Section 5.5.1), a distributed system as specified in the specification of the patent might well have terminals at all of its sites, such an extension only provides the means, but does not show any intent of the `105 patent to allow manual processing (see also Section 1.12 on human intervention). We certainly cannot also extend the claims to enlarge the critical function of determining the appropriateness of the treatment, and include a second source (the provider's discussion of the patient's Medical History) in addition to the Reimbursement Claims History (the history collected at TRIGON and made available to the manual adjudication process). If such extensions were warranted.

The claim by Holland (see Section 5.6.1) on equivalence of the Patient's Medical History with the Reimbursement Claims History is specious.

Since Trigon performs no automated processing of any kind of patient' history, and Trigon Medical directors can only use the system manually to access a limited reimbursement claims history, the Trigon systems do not infringe on the claims made by the plaintiff.

If the interpretation of the `105 patent is to be so broadly construed to include the actual Trigon operation, then the issue of validity must be raised, since Trigon's predecessors and competitors had access to patient's Reimbursement claim Histories and could call providers on the phone to get information from the patient's Medical History.

2.1.4 Smart Systems.

Trigon does not attempt to identify treatment modes based on a medical history nor on symptoms.

Here we revisit the issue of the major discontinuity, see Section 1.1. These process steps, specified in `105 appear to require the use of a `smart system' or `expert system', as mentioned in the specification. The term `smart system` does not appear in the claims and only appears in the specification. The uniqueness of the patented vision relies on using smart technology to achieve this goal. Its importance is recognized by the patent holder (see Section 5.1.3 and 5.1.4) and by the plaintiff's experts' reports (see Section 5.5.3).

2.1.5 Trigon does not Practice Medicine.

Trigon does not propose medical treatments.
Trigon does not identify proposed modes of treatment.

Trigon does not provide for second opinions

TRIGON provides for reimbursement of treatments proposed and performed by a physician. It provides no feedback to the physician about alternative treatments that might be more effective. A physician may change his mode of practice based on not receiving full or partial reimbursement, how that practice will be altered remains the decision of the practitioner.

Differences about treatment are often due to different value systems. For instance, a physician may seek a more promising treatment, but the patient has an aversion to risk or pain. Sometimes patients have heard about costly or unusual treatments that the physician has rejected as having had little or no additional benefit over commonly accepted alternatives.

Second opinions are a means for a patient to gain confidence for a proposed treatment. Different treatments often reflect different value systems such as aversion to risk, pain, or acceptance in common practice. Trigon provides pre-certification of costly treatments proposed by a provider, but those are based on cost-effectiveness. Any denial of reimbursement for proposed treatment in cases involving medical necessity is made manually by Medically certified personnel at TRIMED system, not by any automated program.

2.1.6 Trigon does not determine preventive care based on Symptoms.

Trigon does not identify preventive health routines based on Symptoms.
Trigon does not propose preventive care based on Symptoms.
Trigon does not tentatively identify preventive health routines based on Symptoms.

Trigon does not tailor wellness recommendations to specific patients, and certainly does not identify nor propose patient-specific preventive health routines or preventive health care based on symptoms reported by the patient. It does not have access to such symptoms; those best remain with the physician.

2.1.7 Ancillary Services including Pharmacy

Trigon does not propose ancillary services.

Trigon does not provide ancillary services.
Trigon does not keep a list of predetermined procedures requiring ancillary services.

Ancillary services cover a wide range of diagnostic services and treatments (see Definition 3.11). In the opinion of the plaintiff's experts, pharmacy services are included when the term is used in the `105 patent. Any prescriptions for medication, normally presented to a Pharmacy, are passed through by TRIGON to an independent operation, MEDCO. In practice, TRIGON is apt to see very few of those, since most prescriptions are brought by the patient to their pharmacies, who then deal with MEDCO or similar drug-management services directly.

Other ancillary services, such as physical rehabilitation, are outside of TRIGON's sphere, since they again involve medical judgment. Such services are proposed by physicians and provided by appropriate specialized health care facilities. Such facilities may submit bills for reimbursement to TRIGON, and those bills will be dealt with in a manner analogous to in-and outpatient billing by hospitals and individual providers, as described in Section 2.1.2. No automatic adjudication of such claims is or should be based on symptoms presented by the patient.

TRIGON does not perform activities within the scope of the ‘105 claims that deal with preventive care.

2.1.8 Illness

We consider the term illness here ill defined.
Trigon does not enter identification of symptoms for diagnosis of illnesses.
Trigon does not enter identification of symptoms for treatment of illnesses.

An illness (see Definition 3.3) is neither a diagnosis nor a treatment procedure. An illness represents a condition of the body or the mind that may be the complex interactions of many diagnoses manifesting as numerous symptoms.

In the accused systems, approval of an inpatient reimbursement claim is based on the contract and the diagnosis of the patient and, if needed, telephonic interaction with the medical staff at the hospital. Similarly, in the accused system, approval of a payment claim for outpatient office visits and referrals is based on the contract and the diagnosis reported by the physician.

Symptom information is not encoded in reimbursement claims for payment. It could be entered on a text field but is not processed automatically, and not even made available to the medical staff associated with the Trimed system.

The ‘105 patent specification and claims require automated processing based on symptoms.

2.2 Trigon System

The Trigon Systems, in their aggregate, form a health insurance reimbursement claims processing system. A reimbursement claim represents a request for a financial transaction on behalf of an individual policyholder and includes diagnosis and treatment information. Reimbursement claims are entered into the system where they are then adjudicated, resulting in financial transactions. Reimbursement claims may enter the system through many avenues, including paper, phone, web clients, or electronic transmission. The adjudication process is shared between two main sub-systems. One of the adjudication sub-systems resolves reimbursement claims that fall within excepted health insurance policy guidelines. The other adjudication sub-system resolve reimbursement claims that require additional medical information. The two sub-systems work together in tandem. The reimbursement claim may be associated with many adjudication sequences resulting in changes to the financial transaction and the reimbursement claim status. An explanation of benefits describes the financial transaction and reimbursement claim status. While many reimbursement claims are post-treatment, some reimbursement claims are pre-treatment to establish a predictable financial transaction outcome and status when the post-treatment reimbursement claim is presented.

In addition to the reimbursement claims processing system, there are several other systems at Trigon. One such system is an informational web site. Another such system is a `Healthy Return' service. Other systems perform data mining of the reimbursement claims data in the aggregate to establish cost effectiveness of policy groups.

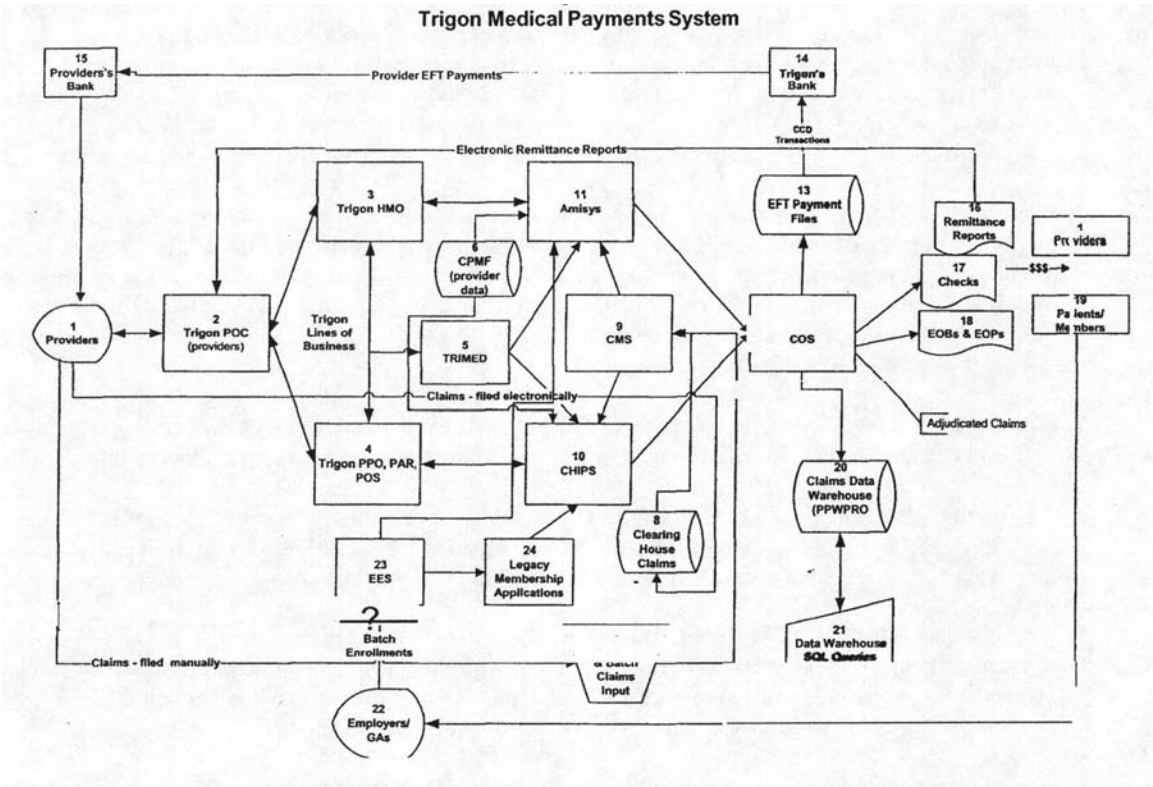


Figure 1: A diagram of Trigon's operations, from the [Kurtyka:2002] expert report.

Figure 1 provides an overview of TRIGON's system architecture as perceived by one of the plaintiff's experts. It shows that TRIGON is a loosely integrated system, as per Definition 3.22. The systems architecture sketched here conflicts with the patent specification

> "the ***integrated*** interconnection and interaction of the patient, health care provider, bank or other financial institution, utilization reviewer/case management and employer so as to include within **a single system** each of the essential elements to provide patients with complete and comprehensive health care and payment therefor. (1 *:55-60).*"

This sentence favors a tightly integrated architecture, where all components are at least managed by a central authority, even if multiple computers and databanks may be in use. Allcare's experts have been inconsistent in their interpretation. Most have favored a loose coupling or a 'distributed system'. However, this is in conflict with Singer, who, when dismissing prior art, states that systems having external components means that those system are not integrated in the sense required by the `105 patent (see Section 5.4).

Some peripheral elements are missing from Figure 1, as FEP, Claims Reimbursement data collection for Federal Employees, processed elsewhere.

Both [Holland:2002] and [Kaliski:2002] give descriptions of the Trigon systems. They also see the TRIGON systems as having a loosely integrated architecture. They believe that such an architecture matches the intent of the '105 patent. We do not herein endorse all aspects of their testimony regarding the Trigon systems. We find that the Trigon systems do not include every element of any asserted claim of the `105 patent.

2.2.1 Overview

We list here the three principal steps involved in processing reimbursement claims, which include all the methods that the plaintiff asserts as being infringed by TRIGON: creation and submission, adjudication, and payment remittance.

2.2.1.1 A Reimbursement Claim is Created.

Reimbursement claims may be created and submitted on paper or through a computer system. Paper claims are sent to an internal service component and converted there to electronic form. Trigon also has a web application that is available to certain physician offices .

A reimbursement claim may be submitted via electronic transmission to **Trigon Open Network** or **MedUnite.** Paper based reimbursement claims are entered into the system using OCR in the CMS component (box 9). Some reimbursement claims require manual entry by a Trigon employee.

Claims for or from Out-of-State members use a clearinghouse (ITS) – box 8.

All reimbursement claims eventually enter the **Claims Management System (CMS** – box 9**)**. In the CMS, claims are checked for syntax errors, obvious exclusions, and scrubbed for consistency. The reimbursement claim is now dispatched to one of many adjudication systems: the **Comprehensive Health Insurance Processing System (CHIPS** – box 10**),** the **Federal Employee Program (FEP),** the **Inter-Plan Teleprocessing System (ITS)**, and the **Amisys** (box 11).

2.2.1.2 A Reimbursement Claim is Adjudicated.

CHIPS adjudicates reimbursement claims that fall within excepted health insurance policy guidelines. CHIPS works in tandem with **TRIMED** (box 5) when a reimbursement claim requires additional medical information. CHIPS validates a member and a provider, prices a reimbursement claim based on policy guidelines, and verifies pre-authorization, pre-certification, and referral information. Pre-authorization, pre-certification, and a referral are not a guaranty of future reimbursement claim adjudication. A reimbursement claim may be put into the "pend"(ing) status if additional medical information is required. This reimbursement claim is now sent to TRIMED for medical-based adjudication.

FEP reimbursement claims are sent off-site to a federal government system for adjudication, then back to **COS (**unnumbered box **)**.

ITS reimbursement claims happen when a policyholder of one Blue-Cross system uses another Blue-Cross system for treatment. ITS handles the case when a Trigon member uses another Blue-Cross system and the case when another Blue-Cross member uses a provider under the Trigon system.

Amisys reimbursement claims are processed by a vendor purchased product and handle the HMO portion of Trigon's business. Reimbursement claims are processed based on managed care arrangements with fixed fees.

All adjudicated reimbursement claims are sent to the **Common Output System (COS).**

2.2.1.3 A Reimbursement Claim's Remittance.

The **Common Output System (COS)** handles the remittance, the **Explanation of Benefits (EOB),** and the writing of reimbursement claims information into the **(Product Profitability Report) PPR**. The PPR is a data warehouse of reimbursement claims information and is used to establish, in aggregate, the profitability of policy groups and programs.

2.2.1.4 Other Trigon Systems and Services.

Professional Forum is a monthly provider newsletter designed to communicate useful information to physicians for managing their practice, as well as up-to-date medical issues.

Healthy Returns is an optional service for health maintenance and screening of health life styles used mainly by members during maternity.

The **Trigon Web Site** is an informational health care site and not associated with reimbursement claims adjudication.

2.2.2 Trigon Sub Systems

We now describe the individual components. We list them in the logical processing order used for Section 2.2.1, followed by a section for secondary systems.
To locate a systems component rapidly, we provide here an alphabetical index for the various systems and their common abbreviation.

- **2.2.2.13 AIMS**
- **2.2.2.5 Amisys**
- **2.2.2.16 Admission Summary Kiosk (ASK)**
- **2.2.2.15 Claim Analysis Report System (CARS and CURS)**
- **2.2.2.4 Comprehensive Health Insurance Processing System (CHIPS)**
- **2.2.2.3 Claims Management System (CMS)**
- **2.2.2.9 Common Output System (COS)**
- **2.2.2.11 Data Pharmacy**
- **2.2.2.12 Enrollment**
- **2.2.2.7 Federal Employee Program (FEP)**
- **2.2.2.18 FSS, now called FAS, Financial audit**
- **2.2.2.14 Healthy Returns Maternity advice**
- **2.2.2.8 Inter-Plan Teleprocessing System (ITS)**
- **2.2.2.2 Open Network a front-end service supplied by MedUnite**
- **2.2.2.10 Payment System with electronic funds transfers and paper checks**
- **2.2.2.19 Performance Reward Program (PEX)**
- **2.2.2.17 Pharmacy Data Mart**
- **2.2.2.1 Point of Care (POC)**
- **2.2.2.20 Product Profitability Report (PPR)**
- **2.2.2.21 Professional Forum**
- **2.2.2.23 Trigon Web Site**
- **2.2.2.6 Trimed, the adjudication system**
- **2.2.2.22 Tutorial and other Training Programs**

2.2.2.1 Point of Care (POC)

Point of Care (POC) is a web-based application with the feature of: patient eligibility verification, verify patient's benefits (copay and deductibles), reimbursement claims status, 151 Forms, Referrals (create, update, view, inquiry) , eReports (weekly remittance, explanations of payment, HMO capitation), reimbursement claim error notification, and inpatient Admissions (pre-certification).

A family member is identified with an ID number. Each member of the family is identified with the triple of name, relationship, and date of birth.

Using this system an individual, usually an administrator at the provider's location, can query for member eligibility, obtain reimbursement claims history per member or per provider, request an adjustment (form 151) to an already existing reimbursement claim and view the results of that request, obtain a remittance statement, obtain reimbursement claim error notification letters, obtain benefit information, submit a referral request and obtain a referral identification number, and request a pre-certification or a pre-authorization.

POC also provides linkages to Open Network (see 2.2.2.2) for electronic reimbursement claims submission and to Professional Forum (see 2.2.2.21), a newsletter.

2.2.2.2 Open Network provides for electronic reimbursement claims submission support by a front-end service supplied by MedUnite. Note that it is actually a proprietary, rather than a public network, also independent from the Internet. In that sense Trigon fails one of [Singer:2000]'s criteria, see Section 5.3.6.

2.2.2.3 Claims Management System(CMS)

The **Claims Management System(CMS)** dispatches all received reimbursement claims. Included in the CMS claims processing are checks for input errors and missing data. The claims are also scrubbed for consistency. Acceptable reimbursement claims are now dispatched to one of several adjudication systems: the **Comprehensive Health Insurance Processing System (CHIPS),** the **Federal Employee Program (FEP),** the **Inter-Plan Teleprocessing System (ITS)**, and **Amisys**. A reimbursement claim rejected for input errors generates a proof-of-loss statement, which is made available to the provider who submitted the claim.

2.2.2.4 The Comprehensive Health Insurance Processing System (CHIPS)

The **Comprehensive Health Insurance Processing System (CHIPS)** adjudicates reimbursement claims that fall within excepted health insurance policy guidelines. CHIPS works in tandem with **TRIMED** when a reimbursement claim requires medically

justified decision-making. CHIPS validates a member and a provider, prices a reimbursement claim based on policy guidelines, and verifies pre-authorization, pre-certification, and referral information. Pre-authorization, pre-certification, and a referral are not a guaranty of future reimbursement claim adjudication. A reimbursement claim may be put into the "pend"(ing) status if additional medical information is required. This reimbursement claim is now sent to TRIMED for medical-based adjudication.

2.2.2.5 Amisys.

Amisys. HMO reimbursement claims are adjudicated by Amisys, a product purchased from an external vendor. Amisys and CHIPS perform similar functions in a similar fashion. Both CHIPS and Amisys work in tandem with TRIMED when a reimbursement claim requires additional medical information. Amisys validates a member, a provider, and a facility, prices an HMO reimbursement claim based on policy guidelines, and verifies pre-authorization, pre-certification, and referral information. Pre-authorization, pre-certification, and a referral are not a guarantee of future HMO reimbursement claim adjudication. An HMO reimbursement claim may be put into the "pend"(ing) status if additional medical information is required. This HMO reimbursement claim is now sent to TRIMED for medical assessment.

HMO reimbursement claims enter the system using paper, fax, phone, or electronic submission. Most of the HMO reimbursement claims are processed in a batch mode fashion. The HMO reimbursement claims are pre-processed and grouped into episodes. Paper, fax, and phone HMO reimbursement claims are processed by MACESS, another purchased product that also acts as a call center for HMO staff.

All adjudicated HMO reimbursement claims are sent to the COS for remittance, EOB, and the writing of a PPR record.

2.2.2.6 Trimed

Trimed performs medical-based adjudication based on medical necessity. This includes the initial approval, identification for pre-authorization, pre-certification, and referrals. A reimbursement claim contains diagnosis and treatment information. Additional medical information that may be needed to adjudicate the reimbursement claim is obtained telephonically. Trained medical employees staff Trimed. There is no automated denial. A MD eventually adjudicates all denials. Though most pre-authorizations, pre-certification, and referrals initial approvals are done pre-treatment, there are provisions and a grace period for post-treatment approvals.

2.2.2.7 Federal Employee Program (FEP)

The **Federal Employee Program (FEP) sends** reimbursement claims for federal employees to an off-site federal government system for adjudication. These are then returned back and enter **COS** for payment remittance.

2.2.2.8 Inter-Plan Teleprocessing System (ITS)

The **Inter-Plan Teleprocessing System (ITS)** processes reimbursement claims occurring when a policyholder of one Blue-Cross system uses another state Blue-Cross system for treatment. ITS handles both cases: 1. the case when a Trigon member uses another Blue-Cross system and, 2. the case when another Blue-Cross member uses a provider under the Trigon aegis.

2.2.2.9 Common Output System (COS)

The **Common Output System (COS)** handles the remittance, the **Explanation of Benefits (EOB),** and the writing of reimbursement claims information into the **(Product Profitability Report) PPR**. COS also updates the general ledger system and generates the Explanation of Benefits (EOB) statements.

2.2.2.10 Payment Systems

Payment Systems at Trigon include electronic funds transfers and issuing traditional paper checks.

2.2.2.11 Data Pharmacy.

Data Pharmacy. A third-party vendor, Medco, processes pharmaceutical reimbursement claims and in some cases laboratory reimbursement claims. A patient presents a prescription to the pharmacy. An electronic reimbursement claim is sent to Medco for adjudication and remittance information is returned, resulting in optional co-pay and the dispensing of the pharmaceutical or the completion of the laboratory procedure. The Medco system uses the National Council for Prescription Drug Programs (NCPDP) standard for reimbursement claims processing as well as drug utilization review dealing with potential drug interactions.

This reimbursement claim adjudication is outside of the scope of Trigon's reimbursement claims processing and remittance systems. A pre-authorization identifier is obtained for some pharmaceutical reimbursement claims using the Point of Care system. A PPR record (see 2.2.2.20) is written for drug claims.

2.2.2.12 Enrollment

Enrollment is a desktop application used to update membership information.

2.2.2.13 AIMS

AIMS is the call center system. Either a member or a provider can place a phone call to AIMS. Reimbursement claim status information can then be viewed and missing reimbursement claims information can be provided. However, a new reimbursement claim cannot be created in AIMS. A record of the conversation, both audio and data, is stored. The last several data records, called Units of Work, are retrieved and presented on the display when the call is routed to the workstation as well as other identifying information. Demographical information may be modified during the call.

2.2.2.14 Healthy Returns

Healthy Returns is a service provided by Health Management Corporation. This is an optional service for members. At the request of the primary care provider and the member, progress relating to preventive health activities are reviewed. This service is mainly used by members during maternity. No data flows back to Trigon. Some data is sent to HMC to stratify potential members who might be interested in the service.

2.2.2.15 CARS and CURS

CARS. The Claim Utilization Report System (CURS) mines the PPR archive of reimbursement claim data, in a retrospective fashion. It aggregates results into Episode Treatment Groups (ETG) using a product from Symmetry. About two years of data is maintained.

The Claim Analysis Report System (CARS) generates a series of internal reports based on the CURS data summarizing profitability aggregated by providers, facilities, pharmaceuticals, or programs. Other statistics are provided including visits per thousand members, hospital inpatient days per thousands, procedures per thousand, and pharmaceutical usage per thousand members. The information from these reports influences future financial rates.

2.2.2.16 Admission Summary Kiosk (ASK)

The Admission Summary Kiosk (ASK) is a similar system to CARS. The ASK system mines data from hospital reimbursement claims from the PPR archive. The 3M based group is used to establish Diagnostic Related Groups (DRG) (See Definition 3.4). A series of internal reports are generated, summarizing profitability aggregated by DRG. Other statistics are provided including Length of Stay (LOS). These statistics are then

compared with data provided by Milliman and Robertson. The information from these reports then influences future financial rates.

2.2.2.17 Pharmacy Data Mart

Trigon's **Pharmacy Data Mart** system post-processes the pharmaceutical reimbursement claims PPR records sent by the pharmacy system, Medco. A complex series of queries seek potential drug therapy problems relating to cost effectiveness of alternative pharmaceuticals, resulting in an informational letter to the primary physician on record. The Drug Pharmacy Mart does NOT suggest a drug treatment. If a drug is prescribed when a lower cost alternative exists, then it makes a suggestion based on cost and not treatment. In addition, financial information, in the aggregate, is mined.

2.2.2.18 FSS

FSS , now called FAS, is a financial audit system at the facility and provider level. This information is mined from the PPR in aggregate.

2.2.2.19 Performance Reward Program.

Performance Reward Program. Provider Profiling is a system based on Soluicent's Peer-a-Med product that ranks primary care physicians associated with either the HMO or the POS plans within their peer group. In a retro-perspective fashion, about a year of PPR reimbursement claim data is mined. Informational reports are generated summarizing direct costs, indirect costs, and average patient cost per episode adjusted for clinical risk. Other statistics include financial information for top diagnoses and top procedures. These reports are then mailed to the provider.

Performance Extra Program (PEX) is a physician incentive program based half on quality indicators and half on financial indications. A score is calculated. A patient satisfaction survey contributes 15% to the score. If the patient is provided tobacco cessation information, another 5% is contributed to the score. If the CDC guidelines are followed indicating adherence to the antibiotic usage guidelines, another 15%is added to the score. If either mammograms or adolescence well visits are indicated, another 15% is contributed to the score. If the provider accepts new patients that are covered under a Trigon policy, another 20% is contributed to the score. If the provider uses Point-of-Care for submission of claims, another 15% is contributed to the score. The provider profiling contributes the remaining 15% to the score. The score will be used to generate an annual financial incentive. This system is described in [ProfessionalForum:2001].

2.2.2.20 Product Profitability Report (PPR)

Product Profitability Report (**PPR)** is a data warehouse of archived reimbursement claims information and is used to establish, in aggregate, the profitability of policy groups and programs. Its contents cannot fulfill the need of a Medical History for patients covered by the organizations served by Trigon. See Sections 3.7 and 3.8 for such distinctions. Data are kept for two years and then periodically removed. In addition to its limited content, it also fails Allcare's witness [Singer:2000]'s criterion of maintaining long-lived data, see Section 5.3.

2.2.2.21 Professional Forum

Professional Forum is a monthly provider newsletter designed to communicate useful information for managing their practice, as well as up-to-date medical issues, and thus does not infringe on the `105 patent.

2.2.2.22 Tutorial

Tutorial and other Training Programs are educational.

2.2.2.23 Trigon Web Site

The **Trigon Web Site** is an information only service.

2.3 Elements of Patent `105 Claim that Disallow Infringement.

The following asserted `105 patent claims are not infringed for the reasons stated in this section. We use Trigon here for the totality of systems available at Trigon. In the next section we address individual systems against which `105 claims have been asserted. To the extent requested, I expect to testify on the facts set forth in Defendants' claim chart and the Defendants' positions set forth in the Joint Claim Chart.

When the reason for disallowing infringement in a dependent claim is due inheritance from its independent predecessor, we have listed the entry in parentheses and prefixed it as (From Claim n ...).

Claim 1. (d) No patient symptom data are available for processing. [See 2.1.2] Trigon does not process symptoms. [See 2.1.2] Trigon does not automatically prevent payment for medical reasons. [See 2.1.1]

Claim 2. Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7] (From Claim1: Trigon does not process symptoms. [See 2.1.2] Trigon does not automatically prevent payment for medical reasons. [See 2.1.1])

Claim 4. (b) Trigon's databanks do not include predetermined items of medical history. [See 2.1.3] (e) Trigon does not process symptoms. [See 2.1.2]

Claim 5. Trigon 's databanks do not include physical profiles. [See 2.1.3] (From Claim 4 (b) Trigon's databanks do not include predetermined items of medical history. [See 2.1.3] (e) Trigon does not process symptoms. [See 2.1.2])

Claim 6. Trigon does not collect predetermined items of medical history. [See 2.1.3] (From Claim 4 (b) Trigon's databanks do not include predetermined items of medical history. [See 2.1.3] (e) TRIGON does not process symptoms. [See 2.1.2])

Claim 7. (From Claim 4 (b) Trigon's databanks do not include predetermined items of medical history. [See 2.1.3] (e) Trigon does not process symptoms. [See 2.1.2])

Claim 8. (From Claim 4 (b) Trigon's databanks do not include predetermined items of medical history. [See 2.1.3] (e) Trigon does not process symptoms. [See 2.1.2].

Claim 9. (From Claim 4 (b) Trigon's databanks do not include predetermined items of medical history. [See 2.1.3] (e) TRIGON does not process symptoms. [See 2.1.2])

Claim 12. (From Claim 4 (b) Trigon's databanks do not include predetermined items of medical history. [See 2.1.3] (e) Trigon does not process symptoms. [See 2.1.2])

Claim 16. (d) No patient symptom data are available for processing at Trigon. [See 2.1.2]

Trigon does not process symptoms. [See 2.1.2] Trigon does not automatically prevent payment for medical reasons. [See 2.1.1] Trigon does not provide for second opinions. [See 2.1.5]

Claim 17. Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7] (From Claim 16 (d) No patient symptom data are available for processing at Trigon. [See 2.1.2] Trigon does not process symptoms. [See 2.1.2] Trigon does not automatically prevent payment for medical reasons. [See 2.1.1] Trigon does not provide for second opinions. [See 2.1.5])

Claim 19. (b) Trigon does not store a medical history. [See 2.1.3] (e) Trigon does not process symptoms. [See 2.1.2] Trigon does not automatically prevent payment for medical reasons. [See 2.1.1] Trigon does not provide for second opinions. [See 2.1.5]

Claim 20. Trigon does not store physical profiles. [See 2.1.3] (From Claim 19 (b) Trigon does not store a medical history. [See 2.1.3] (e) Trigon does not process symptoms. [See 2.1.2] Trigon does not automatically prevent payment for medical reasons. [See 2.1.1] Trigon does not provide for second opinions. [See 2.1.5])

Claim 21. Trigon does not collect predetermined items of medical history. [See 2.1.3] (b) Trigon does not store a medical history. [See 2.1.3] (e) Trigon does not process symptoms. [See 2.1.2] Trigon does not automatically prevent payment for medical reasons. [See 2.1.1] Trigon does not provide for second opinions. [See 2.1.5]

Claim 22. (From Claim 19 (b) Trigon does not store a medical history. [See 2.1.3] (e) Trigon does not process symptoms. [See 2.1.2] Trigon does not automatically prevent payment for medical reasons. [See 2.1.1] Trigon does not provide for second opinions. [See 2.1.5])

Claim 23. (From Claim 19 (b) Trigon does not store a medical history. [See 2.1.3] (e) Trigon does not process symptoms. [See 2.1.2] Trigon does not automatically prevent payment for medical reasons. [See 2.1.1] Trigon does not provide for second opinions. [See 2.1.5])

Claim 24. (From Claim 19 (b) Trigon does not store a medical history. [See 2.1.3] (e) Trigon does not process symptoms. [See 2.1.2] Trigon does not automatically prevent payment for medical reasons. [See 2.1.1] Trigon does not provide for second opinions. [See 2.1.5])

Claim 27. (From Claim 19 (b) Trigon does not store a medical history. [See 2.1.3] (e) Trigon does not process symptoms. [See 2.1.2] Trigon does not automatically prevent payment for medical reasons. [See 2.1.1] Trigon does not provide for second opinions. [See 2.1.5])

Claim 34. (a) Trigon does not collect patient symptoms. [See 2.1.2] (b) Trigon does not store a medical history. [See 2.1.3] (c) Trigon does not keep a list of predetermined

procedures requiring ancillary services. [See 2.1.7] (d) Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7]

Claim 35. Trigon does not store physical profiles. [See 2.1.3] (From Claim 34 (a) Trigon does not collect patient symptoms. [See 2.1.2] (b) Trigon does not store a medical history. [See 2.1.3] (c) Trigon does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7] (d) Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 36. Trigon does not collect predetermined items of medical history. [See 2.1.3] (From Claim 34. (a) Trigon does not collect patient symptoms. [See 2.1.2] (b) Trigon does not store a medical history. [See 2.1.3] (c) Trigon does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7] (d) Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 37. (From Claim 34. (a) Trigon does not collect patient symptoms. [See 2.1.2] (b) Trigon does not store a medical history. [See 2.1.3] (c) Trigon does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7] (d) Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 38. (From Claim 34. (a) Trigon does not collect patient symptoms. [See 2.1.2] (b) Trigon does not store a medical history. [See 2.1.3] (c) Trigon does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7] (d) Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 39. (From Claim 34. (a) Trigon does not collect patient symptoms. [See 2.1.2] (b) Trigon does not store a medical history. [See 2.1.3] (c) Trigon does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7] (d) Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 43. (From Claim 34. (a) Trigon does not collect patient symptoms. [See 2.1.2] (b) Trigon does not store a medical history. [See 2.1.3] (c) Trigon does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7] (d) Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 52. (c) Trigon does not collect patient symptoms. [See 2.1.2] Trigon does not process symptoms. [See 2.1.2] (d) Trigon does not automatically prevent payment for medical reasons. [See 2.1.1]

Claim 53. Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7] (From Claim 52. (c) Trigon does not collect patient

symptoms. [See 2.1.2] Trigon does not process symptoms. [See 2.1.2] (d) Trigon does not automatically prevent payment for medical reasons. [See 2.1.1])

Claim 54. Trigon does not identify preventive health routines based on Symptoms. [See 2.1.6] (From Claim 52. (c) Trigon does not collect patient symptoms. [See 2.1.2] Trigon does not process symptoms. [See 2.1.2] (d) Trigon does not automatically prevent payment for medical reasons. [See 2.1.1])

Claim 55. (b) Trigon does not store a medical history. [See 2.1.3] (d) Trigon does not collect patient symptoms. [See 2.1.2] Trigon does not process symptoms. [See 2.1.2] (e) Trigon does not automatically prevent payment for medical reasons. [See 2.1.1]

Claim 56. The claim wording is incomplete. (From Claim 55. (b) Trigon does not store a medical history. [See 2.1.3] (d) Trigon does not collect patient symptoms. [See 2.1.2] Trigon does not process symptoms. [See 2.1.2] (e) Trigon does not automatically prevent payment for medical reasons. [See 2.1.1])

Claim 57. Trigon does not collect predetermined items of medical history. [See 2.1.3] (From Claim 55. (b) Trigon does not store a medical history. [See 2.1.3] (d) Trigon does not collect patient symptoms. [See 2.1.2] Trigon does not process symptoms. [See 2.1.2] (e) Trigon does not automatically prevent payment for medical reasons. [See 2.1.1])

Claim 58. (From Claim 55. (b) Trigon does not store a medical history. [See 2.1.3] (d) Trigon does not collect patient symptoms. [See 2.1.2] Trigon does not process symptoms. [See 2.1.2] (e) Trigon does not automatically prevent payment for medical reasons. [See 2.1.1])

Claim 59. (From Claim 55. (b) Trigon does not store a medical history. [See 2.1.3] (d) Trigon does not collect patient symptoms. [See 2.1.2] Trigon does not process symptoms. [See 2.1.2] (e) Trigon does not automatically prevent payment for medical reasons. [See 2.1.1])

Claim 60. (From Claim 55. (b) Trigon does not store a medical history. [See 2.1.3] (d) Trigon does not collect patient symptoms. [See 2.1.2] Trigon does not process symptoms. [See 2.1.2] (e) Trigon does not automatically prevent payment for medical reasons. [See 2.1.1])

Claim 63. (From Claim 57. Trigon does not collect predetermined items of medical history. (From Claim 55. (b) Trigon does not store a medical history. [See 2.1.3] (d) Trigon does not collect patient symptoms. [See 2.1.2] Trigon does not process symptoms. [See 2.1.2] (e) Trigon does not automatically prevent payment for medical reasons. [See 2.1.1])

Claim 67. (c) Trigon does not collect patient symptoms. [See 2.1.2] (e) Trigon does not process symptoms. [See 2.1.2] (f) Trigon does not provide for second opinions. [See 2.1.5]

Claim 68. (d) Trigon does not process symptoms automatically. [See 2.1.2] Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7] (From Claim 67. (c) Trigon does not collect patient symptoms. [See 2.1.2] (e) Trigon does not process symptoms. [See 2.1.2] (f) Trigon does not provide for second opinions. [See 2.1.5])

Claim 69. Trigon does not propose preventive care based on Symptoms. [See 2.1.6] (From Claim 67. (c) Trigon does not collect patient symptoms. [See 2.1.2] (e) Trigon does not process symptoms. [See 2.1.2] (f) Trigon does not provide for second opinions. [See 2.1.5])

Claim 70. (c) Trigon does not keep a medical history. [See 2.1.3] (c) Trigon does not provide for second opinions. [See 2.1.5] (d) Trigon does not collect patient symptoms. [See 2.1.2] (f) Trigon does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4] (g) Trigon does not provide for second opinions. [See 2.1.5]

Claim 71. Trigon does not collect physical profiles. [See 2.1.3] (From Claim 70. (c) Trigon does not keep a medical history. [See 2.1.3] (c) Trigon does not provide for second opinions. [See 2.1.5] (d) Trigon does not collect patient symptoms. [See 2.1.2] (f) Trigon does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4] (g) Trigon does not provide for second opinions. [See 2.1.5])

Claim 72. Trigon systems cannot access predetermined items of medical history. [See 2.1.3] (From Claim 70. (c) Trigon does not keep a medical history. [See 2.1.3] (c) Trigon does not provide for second opinions. [See 2.1.5] (d) Trigon does not collect patient symptoms. [See 2.1.2] (f) Trigon does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4] (g) Trigon does not provide for second opinions. [See 2.1.5])

Claim 73. (From Claim 70. (c) Trigon does not keep a medical history. [See 2.1.3] (c) Trigon does not provide for second opinions. [See 2.1.5] (d) Trigon does not collect patient symptoms. [See 2.1.2] (f) Trigon does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4] (g) Trigon does not provide for second opinions. [See 2.1.5])

Claim 74. (From Claim 70. (c) Trigon does not keep a medical history. [See 2.1.3] (c) Trigon does not provide for second opinions. [See 2.1.5] (d) Trigon does not collect patient symptoms. [See 2.1.2] (f) Trigon does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4] (g) Trigon does not provide for second opinions. [See 2.1.5])

Claim 75. (From Claim 70. (c) Trigon does not keep a medical history. [See 2.1.3] (c) Trigon does not provide for second opinions. [See 2.1.5] (d) Trigon does not collect patient symptoms. [See 2.1.2] (f) Trigon does not attempt to identify treatment modes

based on a medical history nor on symptoms. [See 2.1.4] (g) Trigon does not provide for second opinions. [See 2.1.5])

Claim 78. (From Claim 72. Trigon systems cannot access predetermined items of medical history. [See 2.1.3] (From Claim 70. (c) Trigon does not keep a medical history. [See 2.1.3] (c) Trigon does not provide for second opinions. [See 2.1.5] (d) Trigon does not collect patient symptoms. [See 2.1.2] (f) Trigon does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4] (g) Trigon does not provide for second opinions. [See 2.1.5]))

Claim 80. We consider the term illness here ill defined. [See 2.1.8] (From Claim 70. (c) Trigon does not keep a medical history. [See 2.1.3] (c) Trigon does not provide for second opinions. [See 2.1.5] (d) Trigon does not collect patient symptoms. [See 2.1.2] (f) Trigon does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4] (g) Trigon does not provide for second opinions. [See 2.1.5])

Claim 85. (c) Trigon does not keep predetermined items of medical history. [See 2.1.3] (d) Trigon does not process medical histories. [See 2.1.3] Trigon does not identify proposed modes of treatment. [See 2.1.5] Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7]

Claim 86. Trigon does not collect physical profiles. [See 2.1.3] (From Claim 85. (c) Trigon does not keep predetermined items of medical history. [See 2.1.3] (d) Trigon does not process medical histories. [See 2.1.3] Trigon does not identify proposed modes of treatment. [See 2.1.5] Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 87. Trigon does not collect predetermined items of medical history. [See 2.1.3] (From Claim 85. (c) Trigon does not keep predetermined items of medical history. [See 2.1.3] (d) Trigon does not process medical histories. [See 2.1.3] Trigon does not identify proposed modes of treatment. [See 2.1.5] Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 88. (From Claim 87. Trigon does not collect predetermined items of medical history. [See 2.1.3] (From Claim 85. (c) Trigon does not keep predetermined items of medical history. [See 2.1.3] (d) Trigon does not process medical histories. [See 2.1.3] Trigon does not identify proposed modes of treatment. [See 2.1.5] Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 89. (From Claim 88. (From Claim 87. Trigon does not collect predetermined items of medical history. [See 2.1.3] (From Claim 85. (c) Trigon does not keep predetermined items of medical history. [See 2.1.3] (d) Trigon does not process medical histories. [See 2.1.3] Trigon does not identify proposed modes of treatment. [See 2.1.5] Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 91. Trigon does not tentatively identify preventive health routines based on Symptoms. [See 2.1.6] (From Claim 85. (c) Trigon does not keep predetermined items of medical history. [See 2.1.3] (d) Trigon does not process medical histories. [See 2.1.3] Trigon does not identify proposed modes of treatment. [See 2.1.5] Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 93. (From Claim 87. Trigon does not collect predetermined items of medical history. [See 2.1.3] (From Claim 85. (c) Trigon does not keep predetermined items of medical history. [See 2.1.3] (d) Trigon does not process medical histories. [See 2.1.3] Trigon does not identify proposed modes of treatment. [See 2.1.5] Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 94. We consider the term illness ill defined. [See 2.1.8] Trigon has not entered identification of symptoms for diagnosis of illnesses. [See 2.1.8] (From Claim 85. (c) Trigon does not keep predetermined items of medical history. [See 2.1.3] (d) Trigon does not process medical histories. [See 2.1.3] Trigon does not identify proposed modes of treatment. [See 2.1.5] Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 95. We consider the term illness ill defined. [See 2.1.8] Trigon has not entered identification of symptoms for treatment of illnesses. [See 2.1.8] (From Claim 85. (c) Trigon does not keep predetermined items of medical history. [See 2.1.3] (d) Trigon does not process medical histories. [See 2.1.3] Trigon does not identify proposed modes of treatment. [See 2.1.5] Trigon does not propose ancillary services. [See 2.1.7] Trigon does not provide ancillary services. [See 2.1.7])

Claim 102. (b) Trigon does not collect a personal health profile data for each of a predetermined plurality of persons. [See 2.1.3] (d) Trigon does not provide for second opinions. [See 2.1.5] (e) Trigon does not propose medical treatments. [See 2.1.5]

In summary, all of the asserted `105 claims, when properly interpreted contain limitations that are not identically contained in Trigon's systems or performed by Trigon's operations. In addition, the Trigon systems and operations are not the equivalent of what is set forth in any of the asserted claims as they do not perform substantially the functions in substantially the same way to obtain substantially the same results. In the following Section 2.4 we will expand the non-infringement observations by showing how none of the subsystems involved in Trigon's operations infringe on the claims that the plaintiffs assert against them.

2.4 Accused Component Systems

The following asserted `105 patent claims are not infringed by the accused Trigon systems for the reasons stated in this section. In the following section a numbered claim indicates a direct accusation while a numbered claim in parenthesis indicates an accusation by reference. They are listed in the order presented by the plaintiff. Specifics of the systems are provided in Section 2.2.

2.4.1 Trigon Web Site

The **Trigon Web Site** is an information site and does not infringe on Claims 1, 1b, (4c), 52, 52b, 54, (55c), (69), (85d), (91), (102a), (102b), (102c), 102d, and (102f) as directly or indirectly accused.

Not in the scope of the `105 patent.

2.4.2 Trimed

Trimed does not infringe on Claims 1, 1b, 1d, 2, 4b, (4c), (4e), (5), (6), (16d), (17), (19b), (19e), (20), (21), (34a), (34b), (34c), (34d), (35), (36), (37), (38), (39) , (52), (52d), (53), (55b), (55e), (56) , (56), (67f), (68), (70b), (70g), (71), (72), (85c) , (85d), (85e), (86), (87) , (102a) , (102b) , (102c), (102d), (102e), and (102g) as directly or indirectly accused.

Trimed does not automatically prevent payment for medical reasons. [See 2.1.1]
No patient symptom data are available for processing. [See 2.1.2]
Trimed does not process symptoms. [See 2.1.2]
Trimed does not collect patient symptoms. [See 2.1.2]
Trimed does not process symptoms automatically. [See 2.1.2]
Trimed databanks do not include predetermined items of medical history. [See 2.1.3]
Trimed systems cannot access predetermined items of medical history. [See 2.1.3]
Trimed does not collect predetermined items of medical history. [See 2.1.3]
Trimed does not keep predetermined items of medical history. [See 2.1.3]
Trimed 's databanks do not include physical profiles. [See 2.1.3]
Trimed does not store a medical history. [See 2.1.3]
Trimed does not store physical profiles. [See 2.1.3]
Trimed does not collect physical profiles. [See 2.1.3]
Trimed does not keep a medical history. [See 2.1.3]
Trimed does not process medical histories. [See 2.1.3]
Trimed does not collect a personal health profile data for each of a predetermined plurality of persons. [See 2.1.3]
Trimed does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
Trimed does not provide for second opinions. [See 2.1.5]

Trimed does not identify proposed modes of treatment. [See 2.1.5]
Trimed does not propose medical treatments. [See 2.1.5]
Trimed does not propose ancillary services. [See 2.1.7]
Trimed does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7]
Trimed does not provide ancillary services. [See 2.1.7]

2.4.3 Enterprise Network

The **Enterprise Network** is an unidentifiable accused system.

2.4.4 Open Network

The **Open Network** does not infringe on Claims 1, 1c, 1d, (4d), (4e), (16c), (16d), (19d), (19e), (52), 52a, (52d), (55e), (67d), (70e), and (102g) as directly or indirectly accused.

Open Network does not automatically prevent payment for medical reasons. [See 2.1.1]
No patient symptom data are available for processing. [See 2.1.2]
Open Network does not process symptoms. [See 2.1.2]
Open Network does not collect patient symptoms. [See 2.1.2]
Open Network's databanks do not include predetermined items of medical history. [See 2.1.3]
Open Network does not store a medical history. [See 2.1.3]
Open Network does not keep a medical history. [See 2.1.3]
Open Network does not collect a personal health profile data for each of a predetermined plurality of persons. [See 2.1.3]
Open Network does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
Open Network does not provide for second opinions. [See 2.1.5]
Open Network does not propose medical treatments. [See 2.1.5]

2.4.5 Point of Care

Point of Care does not infringe on Claims 1, 1a, 1b, 1c, 1d, 2, 4a, 4b, (4c), (4d), (4e), (5), (6), 7, 8, 9, (12), (16a), 16b, (16c), (16d), (17), (19a), (19b), 19c, (19d), (19e), (20), (21), 22, 23, 24, (27), (34a), (34b), (34c), (34d), (35), (36), (37), (38), (39), (43), 52, 52a, 52b, 52c, (52d), (53), 55a, (55b), (55c), (55d), (55e), (56), 58, 59, 60, (63), (67a), (67b), 67c, 67e, (67f), (68), (70a), (70b), (70c), (70d), (70e), 70f,, (70g), (71), (72), 73, 74, 75, (78), 80, (85a), (85b), (85c), (85d), (85e), (86), (87), 88, 89, (93), 95, (102a), 102b, (102c), (102d), 102e, 102f, and (102g) as directly or indirectly accused.

Point of Care does not automatically prevent payment for medical reasons. [See 2.1.1]
No patient symptom data are available for processing. [See 2.1.2]
Point of Care does not process symptoms. [See 2.1.2]
Point of Care does not collect patient symptoms. [See 2.1.2]
Point of Care does not process symptoms automatically. [See 2.1.2]

Point of Care has not entered identification of symptoms for treatment of illnesses. [See 2.1.8]
Point of Care's databanks do not include predetermined items of medical history. [See 2.1.3]
Point of Care 's databanks do not include physical profiles. [See 2.1.3]
Point of Care does not collect predetermined items of medical history. [See 2.1.3]
Point of Care systems cannot access predetermined items of medical history. [See 2.1.3]
Point of Care does not keep predetermined items of medical history. [See 2.1.3]
Point of Care does not collect a personal health profile data for each of a predetermined plurality of persons. [See 2.1.3]
Point of Care does not store a medical history. [See 2.1.3]
Point of Care does not store physical profiles. [See 2.1.3]
Point of Care does not keep a medical history. [See 2.1.3]
Point of Care does not process medical histories. [See 2.1.3]
Point of Care does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
Point of Care does not provide for second opinions. [See 2.1.5]
Point of Care does not identify proposed modes of treatment. [See 2.1.5]
Point of Care does not propose medical treatments. [See 2.1.5]
Point of Care does not propose ancillary services. [See 2.1.7]
Point of Care does not provide ancillary services. [See 2.1.7]
Point of Care does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7]
We consider the term illness here ill defined. [See 2.1.8]

2.4.6 Performance Reward Program

Performance Reward Program does not infringe on Claims 1a, (4a) , (6) , (12) , (16a) , (19a) , (21) , (27) , (34a) , (36) , (43) , (52) , (56) , (63) , (67a) , (70a) , (72) , (78) , (85a) , (85b) , (87) , and (93) as directly or indirectly accused.

Performance Reward Program does not automatically prevent payment for medical reasons. [See 2.1.1]
No patient symptom data are available for processing. [See 2.1.2]
Performance Reward Program does not process symptoms. [See 2.1.2]
No patient symptom data are available for processing at Performance Reward Program. [See 2.1.2]
Performance Reward Program does not collect patient symptoms. [See 2.1.2]
Performance Reward Program's databanks do not include predetermined items of medical history. [See 2.1.3]
Performance Reward Program does not collect predetermined items of medical history. [See 2.1.3]
Performance Reward Program does not store a medical history. [See 2.1.3]
Performance Reward Program does not keep a medical history. [See 2.1.3]
Performance Reward Program does not process medical histories. [See 2.1.3]

Performance Reward Program systems cannot access predetermined items of medical history. [See 2.1.3]
Performance Reward Program does not keep predetermined items of medical history. [See 2.1.3]
Performance Reward Program does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
Performance Reward Program does not provide for second opinions. [See 2.1.5]
Performance Reward Program does not identify proposed modes of treatment. [See 2.1.5]
Performance Reward Program does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7]
Performance Reward Program does not propose ancillary services. [See 2.1.7]
Performance Reward Program does not provide ancillary services. [See 2.1.7]

2.4.7 Tutorial

Tutorial and other training programs are educational services and do not infringe on Claims 1a, (4a), (6), (12) , (16a) , (19a) , (21) , (27) , (34a) , (36) , (43) , (52) , (56) , (63) , (67a) , (70a) , (72) , (78) , (85a) , (85b) , (87) , and (93) as directly or indirectly accused.

Not in the scope of the `105 patent.

2.4.8 Professional Forum

Professional Forum is an informational newsletter and does not infringe on Claims 1a, 1b, (4a), (4c) , (6) , (12) , (16a) , (19a) , (21) , (27) , (34a) , (36) , (43) , (52) , 52b, (55c) , (56) , (63) , (67a) , (67b) , (70a) , (70c) , (72) , (78) , (85a) , (85b) , (85d) , (87) , (93) , (102c) , (102d) , and (102f) as directly or indirectly accused.

Not in the scope of the `105 patent.

2.4.9 Provider Office Computers used in Point of Care

Provider Office Computers used in Point of Care do not infringe on Claims 1a, (4a), (6), (12), (16a), (19a), (21), (27), (34a), (36), (43), (52), (56), (63), (67a), (70a), (72), (78), (85a), (85b), (87), and (93) as directly or indirectly accused.

Provider Office Computers used in Point of Care do not automatically prevent payment for medical reasons. [See 2.1.1]
No patient symptom data are available for processing. [See 2.1.2]
Provider Office Computers used in Point of Care do not process symptoms. [See 2.1.2]
No patient symptom data are available for processing at Provider Office Computers used in Point of Care. [See 2.1.2]
Provider Office Computers used in Point of Care do not collect patient symptoms. [See 2.1.2]
Provider Office Computers used in Point of Care's databanks do not include predetermined items of medical history. [See 2.1.3]

Provider Office Computers used in Point of Care do not collect predetermined items of medical history. [See 2.1.3]
Provider Office Computers used in Point of Care do not store a medical history. [See 2.1.3]
Provider Office Computers used in Point of Care do not keep a medical history. [See 2.1.3]
Provider Office Computers used in Point of Care do not process medical histories. [See 2.1.3]
Provider Office Computers used in Point of Care systems cannot access predetermined items of medical history. [See 2.1.3]
Provider Office Computers used in Point of Care do not keep predetermined items of medical history. [See 2.1.3]
Provider Office Computers used in Point of Care do not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
Provider Office Computers used in Point of Care do not provide for second opinions. [See 2.1.5]
Provider Office Computers used in Point of Care do not identify proposed modes of treatment. [See 2.1.5]
Provider Office Computers used in Point of Care do not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7]
Provider Office Computers used in Point of Care do not propose ancillary services. [See 2.1.7]
Provider Office Computers used in Point of Care do not provide ancillary services. [See 2.1.7]

2.4.10 Amisys

Amisys does not infringe on Claims 1b, 1c, 1d, 4b, (4c) , (4d) , (4e) , (5) , (6) , (16c) , (16d) , (19b) , (19d) , (19e) , (20) , (21) , (34a) , (34b) , (35) , (36) , (52) , (52d) , (55b) , (55e) , (56) , (56) , (67d) , (67f) , (70b) , (70e) , (70g) , (71) , (72) , (85c) , (85d) , (86) , (87) , (102a) , (102b) , (102c) , (102d) , (102e) , and (102g) as directly or indirectly accused.

Amisys does not automatically prevent payment for medical reasons. [See 2.1.1]
No patient symptom data are available for processing. [See 2.1.2]
Amisys does not process symptoms. [See 2.1.2]
No patient symptom data are available for processing at Amisys. [See 2.1.2]
Amisys does not collect patient symptoms. [See 2.1.2]
Amisys does not store a medical history. [See 2.1.3]
Amisys does not store physical profiles. [See 2.1.3]
Amisys does not collect predetermined items of medical history. [See 2.1.3]
Amisys does not keep a medical history. [See 2.1.3]
Amisys does not collect physical profiles. [See 2.1.3]
Amisys systems cannot access predetermined items of medical history. [See 2.1.3]
Amisys does not keep predetermined items of medical history. [See 2.1.3]
Amisys does not process medical histories. [See 2.1.3]

Amisys does not collect predetermined items of medical history. [See 2.1.3]
Amisys does not collect a personal health profile data for each of a predetermined plurality of persons. [See 2.1.3]
Amisys's databanks do not include predetermined items of medical history. [See 2.1.3]
Amisys 's databanks do not include physical profiles. [See 2.1.3]
Amisys does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
Amisys does not provide for second opinions. [See 2.1.5]
Amisys does not identify proposed modes of treatment. [See 2.1.5]
Amisys does not propose medical treatments. [See 2.1.5]
Amisys does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7]
Amisys does not propose ancillary services. [See 2.1.7]
Amisys does not provide ancillary services. [See 2.1.7]

2.4.11 CMS

CMS does not infringe on Claims 1b, 1c, 1d, (4c), (4d), (4e) , (16c) , (16d) , (19d) , (19e) , (52) , (52d) , (55e) , (67d) , (67f) , (70e) , (70g) , (85d) , (102c) , (102d) , and (102g) as directly or indirectly accused.

CMS does not automatically prevent payment for medical reasons. [See 2.1.1]
No patient symptom data are available for processing. [See 2.1.2]
No patient symptom data are available for processing at CMS. [See 2.1.2]
CMS does not process symptoms. [See 2.1.2]
CMS does not collect patient symptoms. [See 2.1.2]
CMS's databanks do not include predetermined items of medical history. [See 2.1.3]
CMS does not store a medical history. [See 2.1.3]
CMS does not keep a medical history. [See 2.1.3]
CMS does not keep predetermined items of medical history. [See 2.1.3]
CMS does not process medical histories. [See 2.1.3]
CMS does not collect a personal health profile data for each of a predetermined plurality of persons. [See 2.1.3]
CMS does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
CMS does not provide for second opinions. [See 2.1.5]
CMS does not identify proposed modes of treatment. [See 2.1.5]
CMS does not propose medical treatments. [See 2.1.5]
CMS does not propose ancillary services. [See 2.1.7]
CMS does not provide ancillary services. [See 2.1.7]

2.4.12 CHIPS

CHIPS does not infringe on Claims 1b, 1c, 1d, 4b, (4c), (4d), (4e), (5), (6), (16c), (16d), (19b), (19d), (19e), (20), (21), (34a), (34b), (35), (36), (52), (52d), (55b), (55e), (56),

(56), (67d), (67f), (70b), (70e), (70g), (71), (72), (85c), (85d), (86), (87), (102a), (102b), (102c), (102d), (102e), and (102g) as directly or indirectly accused.

CHIPS does not automatically prevent payment for medical reasons. [See 2.1.1]
No patient symptom data are available for processing. [See 2.1.2]
No patient symptom data are available for processing at CHIPS. [See 2.1.2]
CHIPS does not process symptoms. [See 2.1.2]
CHIPS does not collect patient symptoms. [See 2.1.2]
CHIPS does not store a medical history. [See 2.1.3]
CHIPS does not store physical profiles. [See 2.1.3]
CHIPS does not collect predetermined items of medical history. [See 2.1.3]
CHIPS does not keep a medical history. [See 2.1.3]
CHIPS does not collect physical profiles. [See 2.1.3]
CHIPS systems cannot access predetermined items of medical history. [See 2.1.3]
CHIPS does not keep predetermined items of medical history. [See 2.1.3]
CHIPS does not process medical histories. [See 2.1.3]
CHIPS does not collect predetermined items of medical history. [See 2.1.3]
CHIPS does not collect a personal health profile data for each of a predetermined plurality of persons. [See 2.1.3]
CHIPS's databanks do not include predetermined items of medical history. [See 2.1.3]
CHIPS 's databanks do not include physical profiles. [See 2.1.3]
CHIPS does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
CHIPS does not provide for second opinions. [See 2.1.5]
CHIPS does not identify proposed modes of treatment. [See 2.1.5]
CHIPS does not propose medical treatments. [See 2.1.5]
CHIPS does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7]
CHIPS does not propose ancillary services. [See 2.1.7]
CHIPS does not provide ancillary services. [See 2.1.7]

2.4.13 PPR

PPR does not infringe on Claims 1b, 4b, (4c), (5), (6), (19b), (20), (21), (34a), (34b), (35), (36), (52), 54, (55b), (56), (69), (70b), (71), (72), (85c), (85d), (86), (87), (91), (102a), (102b), (102c), (102d), (102e), and (102f) as directly or indirectly accused.

PPR does not automatically prevent payment for medical reasons. [See 2.1.1]
No patient symptom data are available for processing. [See 2.1.2]
PPR does not process symptoms. [See 2.1.2]
PPR does not collect patient symptoms. [See 2.1.2]
PPR's databanks do not include predetermined items of medical history. [See 2.1.3]
PPR 's databanks do not include physical profiles. [See 2.1.3]
PPR does not collect predetermined items of medical history. [See 2.1.3]
PPR does not store a medical history. [See 2.1.3]
PPR does not store physical profiles. [See 2.1.3]

PPR does not keep a medical history. [See 2.1.3]
PPR does not collect physical profiles. [See 2.1.3]
PPR systems cannot access predetermined items of medical history. [See 2.1.3]
PPR does not keep predetermined items of medical history. [See 2.1.3]
PPR does not process medical histories. [See 2.1.3]
PPR does not collect a personal health profile data for each of a predetermined plurality of persons. [See 2.1.3]
PPR does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
PPR does not provide for second opinions. [See 2.1.5]
PPR does not identify preventive health routines based on Symptoms. [See 2.1.6]
PPR does not propose preventive care based on Symptoms. [See 2.1.6]
PPR does not identify proposed modes of treatment. [See 2.1.5]
PPR does not tentatively identify preventive health routines based on Symptoms. [See 2.1.6]
PPR does not propose medical treatments. [See 2.1.5]
PPR does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7]
PPR does not propose ancillary services. [See 2.1.7]
PPR does not provide ancillary services. [See 2.1.7]

2.4.14 Unnamed Databases

Unnamed Databases are vague, but we will interpret it liberally by considering all claims that have a databank component. Trigon databases do not infringe on Claims 1b, 4b, (4c) , (5) , (6), 7, 8, 9, (19b) , (20) , (21) , (34a) , (34b) , (35) , (36) , (52) , (55b) , (55c) , (56) , (56) , (70b) , (71) , (72) , (85c) , (85d) , (86) , (87) , (102a) , (102b) , (102c) , (102d) , and (102e) as directly or indirectly accused.

UNKNOWN DATABASE does not automatically prevent payment for medical reasons. [See 2.1.1]
No patient symptom data are available for processing. [See 2.1.2]
UNKNOWN DATABASE does not process symptoms. [See 2.1.2]
UNKNOWN DATABASE does not collect patient symptoms. [See 2.1.2]
UNKNOWN DATABASE's databanks do not include predetermined items of medical history. [See 2.1.3]
UNKNOWN DATABASE 's databanks do not include physical profiles. [See 2.1.3]
UNKNOWN DATABASE does not collect predetermined items of medical history. [See 2.1.3]
UNKNOWN DATABASE does not store a medical history. [See 2.1.3]
UNKNOWN DATABASE does not store physical profiles. [See 2.1.3]
UNKNOWN DATABASE does not keep a medical history. [See 2.1.3]
UNKNOWN DATABASE does not collect physical profiles. [See 2.1.3]
UNKNOWN DATABASE systems cannot access predetermined items of medical history. [See 2.1.3]

UNKNOWN DATABASE does not keep predetermined items of medical history. [See 2.1.3]
UNKNOWN DATABASE does not process medical histories. [See 2.1.3]
UNKNOWN DATABASE does not collect a personal health profile data for each of a predetermined plurality of persons. [See 2.1.3]
UNKNOWN DATABASE does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
UNKNOWN DATABASE does not provide for second opinions. [See 2.1.5]
UNKNOWN DATABASE does not identify preventive health routines based on Symptoms. [See 2.1.6]
UNKNOWN DATABASE does not propose preventive care based on Symptoms. [See 2.1.6]
UNKNOWN DATABASE does not identify proposed modes of treatment. [See 2.1.5]
UNKNOWN DATABASE does not tentatively identify preventive health routines based on Symptoms. [See 2.1.6]
UNKNOWN DATABASE does not propose medical treatments. [See 2.1.5]
UNKNOWN DATABASE does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7]
UNKNOWN DATABASE does not propose ancillary services. [See 2.1.7]
UNKNOWN DATABASE does not provide ancillary services. [See 2.1.7]

2.4.15 Payment System

Payment System is vague. We interpret liberally as all the Payment systems operated by Trigon. They do not infringe on Claims 1c, (4d), (16c), (19d), (52), (67d), and (70e) as directly or indirectly accused.

PAYMENT SYSTEM does not automatically prevent payment for medical reasons. [See 2.1.1]
No patient symptom data are available for processing. [See 2.1.2]
No patient symptom data are available for processing at PAYMENT SYSTEM. [See 2.1.2]
PAYMENT SYSTEM does not process symptoms. [See 2.1.2]
PAYMENT SYSTEM does not collect patient symptoms. [See 2.1.2]
PAYMENT SYSTEM's databanks do not include predetermined items of medical history. [See 2.1.3]
PAYMENT SYSTEM does not store a medical history. [See 2.1.3]
PAYMENT SYSTEM does not keep a medical history. [See 2.1.3]
PAYMENT SYSTEM does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
PAYMENT SYSTEM does not provide for second opinions. [See 2.1.5]

2.4.16 COS

COS does not infringe on Claims 1c, (4d), (16c), (19d), (52), (67d), and (70e) as directly or indirectly accused.

COS does not automatically prevent payment for medical reasons. [See 2.1.1]
No patient symptom data are available for processing. [See 2.1.2]
No patient symptom data are available for processing at COS. [See 2.1.2]
COS does not process symptoms. [See 2.1.2]
COS does not collect patient symptoms. [See 2.1.2]
COS's databanks do not include predetermined items of medical history. [See 2.1.3]
COS does not store a medical history. [See 2.1.3]
COS does not keep a medical history. [See 2.1.3]
COS does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
COS does not provide for second opinions. [See 2.1.5]

2.4.17 FSS

FSS does not infringe on Claims 1c, (4d), (16c), (19d), (52), (67d) , and (70e) as directly or indirectly accused.

FSS does not automatically prevent payment for medical reasons. [See 2.1.1]
No patient symptom data are available for processing. [See 2.1.2]
No patient symptom data are available for processing at FSS. [See 2.1.2]
FSS does not process symptoms. [See 2.1.2]
FSS does not collect patient symptoms. [See 2.1.2]
FSS's databanks do not include predetermined items of medical history. [See 2.1.3]
FSS does not store a medical history. [See 2.1.3]
FSS does not keep a medical history. [See 2.1.3]
FSS does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
FSS does not provide for second opinions. [See 2.1.5]

2.4.18 payerpath.com

payerpath.com is not a Trigon system.

Not in the scope of this report.

2.4.19 Systems at the Medical College of Virginia

Systems at the Medical College of Virginia are not Trigon systems.

Not in the scope of this report.

2.4.20 Bon Secours Health Systems

Bon Secours Health Systems are not Trigon systems.

Not in the scope of this report.

2.4.21 Columbia/HCA

Columbia/HCA is not a Trigon system.

Not in the scope of this report.

2.4.22 Provider-based Practice Management Systems

Provider-based Practice Management Systems are not Trigon systems.

Not in the scope of this report.

2.4.23 CARS

CARS does not infringe on Claims 4b, (5), (6), (19b), (20), (21), (34a), (34b), (35), (36), (52), (55b), (56), (70b), (71), (72), (85c), (86), (87), (102a), (102b), and (102e) as directly or indirectly accused.

CARS does not automatically prevent payment for medical reasons. [See 2.1.1]
CARS does not process symptoms. [See 2.1.2]
CARS does not collect patient symptoms. [See 2.1.2]
CARS's databanks do not include predetermined items of medical history. [See 2.1.3]
CARS 's databanks do not include physical profiles. [See 2.1.3]
CARS does not collect predetermined items of medical history. [See 2.1.3]
CARS does not keep predetermined items of medical history. [See 2.1.3]
CARS does not store a medical history. [See 2.1.3]
CARS does not process medical histories. [See 2.1.3]
CARS does not store physical profiles. [See 2.1.3]
CARS does not collect physical profiles. [See 2.1.3]
CARS does not keep a medical history. [See 2.1.3]
CARS systems cannot access predetermined items of medical history. [See 2.1.3]
CARS does not collect a personal health profile data for each of a predetermined plurality of persons. [See 2.1.3]
CARS does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
CARS does not provide for second opinions. [See 2.1.5]
CARS does not identify proposed modes of treatment. [See 2.1.5]
CARS does not propose medical treatments. [See 2.1.5]
CARS does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7]
CARS does not propose ancillary services. [See 2.1.7]
CARS does not provide ancillary services. [See 2.1.7]

2.4.24 ASK

ASK does not infringe on Claims 4b, (5), (6), (19b), (20), (21), (34a), (34b), (35), (36), (52), (55b), (56), (70b), (71), (72), (85c), (86), (87), (102a), (102b), and (102e) as directly or indirectly accused.

ASK does not automatically prevent payment for medical reasons. [See 2.1.1]
ASK does not process symptoms. [See 2.1.2]
ASK does not collect patient symptoms. [See 2.1.2]
ASK's databanks do not include predetermined items of medical history. [See 2.1.3]
ASK 's databanks do not include physical profiles. [See 2.1.3]
ASK does not collect predetermined items of medical history. [See 2.1.3]
ASK does not keep predetermined items of medical history. [See 2.1.3]
ASK does not store a medical history. [See 2.1.3]
ASK does not process medical histories. [See 2.1.3]
ASK does not store physical profiles. [See 2.1.3]
ASK does not collect physical profiles. [See 2.1.3]
ASK does not keep a medical history. [See 2.1.3]
ASK systems cannot access predetermined items of medical history. [See 2.1.3]
ASK does not collect a personal health profile data for each of a predetermined plurality of persons. [See 2.1.3]
ASK does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
ASK does not provide for second opinions. [See 2.1.5]
ASK does not identify proposed modes of treatment. [See 2.1.5]
ASK does not propose medical treatments. [See 2.1.5]
ASK does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7]
ASK does not propose ancillary services. [See 2.1.7]
ASK does not provide ancillary services. [See 2.1.7]

2.4.25 Data Pharmacy

Data Pharmacy does not infringe on Claims 4b, (5), (6), (19b), (20), (21), (34a), (34b), (35), (36), (52), (55b), (56), (56), (70b), (71), (72), (85c), (86), (87), (102a), (102b), and (102e) as directly or indirectly accused.

DATA PHARMACY does not automatically prevent payment for medical reasons. [See 2.1.1]
DATA PHARMACY does not process symptoms. [See 2.1.2]
DATA PHARMACY does not collect patient symptoms. [See 2.1.2]
DATA PHARMACY's databanks do not include predetermined items of medical history. [See 2.1.3]
DATA PHARMACY 's databanks do not include physical profiles. [See 2.1.3]
DATA PHARMACY does not collect predetermined items of medical history. [See 2.1.3]
DATA PHARMACY does not keep predetermined items of medical history. [See 2.1.3]
DATA PHARMACY does not store a medical history. [See 2.1.3]

DATA PHARMACY does not process medical histories. [See 2.1.3]
DATA PHARMACY does not store physical profiles. [See 2.1.3]
DATA PHARMACY does not collect physical profiles. [See 2.1.3]
DATA PHARMACY does not keep a medical history. [See 2.1.3]
DATA PHARMACY systems cannot access predetermined items of medical history. [See 2.1.3]
DATA PHARMACY does not collect a personal health profile data for each of a predetermined plurality of persons. [See 2.1.3]
DATA PHARMACY does not attempt to identify treatment modes based on a medical history nor on symptoms. [See 2.1.4]
DATA PHARMACY does not provide for second opinions. [See 2.1.5]
DATA PHARMACY does not identify proposed modes of treatment. [See 2.1.5]
DATA PHARMACY does not propose medical treatments. [See 2.1.5]
DATA PHARMACY does not keep a list of predetermined procedures requiring ancillary services. [See 2.1.7]
DATA PHARMACY does not propose ancillary services. [See 2.1.7]
DATA PHARMACY does not provide ancillary services. [See 2.1.7]

2.4.26 Provider-based Electronic Medical Records

Provider-based Electronic Medical Records are not Trigon systems.

Not in the scope of this report.

2.4.27 AIMS

AIMS does not infringe on Claims 7, 8, and 9 as directly or indirectly accused.

AIMS's databanks do not include predetermined items of medical history. [See 2.1.3]

AIMS does not process symptoms. [See 2.1.2]

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2.4.28 BEX

BEX is an unknown system.

Not in the scope of this report.

2.4.29 Enrollment

Enrollment does not infringe on Claims 7, 8, and 9 as directly or indirectly accused.

Enrollment's databanks do not include predetermined items of medical history. [See 2.1.3]

Enrollment does not process symptoms. [See 2.1.2]

2.4.30 Healthy Returns

Healthy Returns does not infringe on Claims 54 and (91) as directly or indirectly accused.

Healthy Returns does not identify preventive health routines based on Symptoms. [See 2.1.6]
Healthy Returns does not collect patient symptoms. [See 2.1.2]
Healthy Returns does not process symptoms. [See 2.1.2]
Healthy Returns does not automatically prevent payment for medical reasons. [See 2.1.1]
Healthy Returns does not tentatively identify preventive health routines based on Symptoms. [See 2.1.6]
Healthy Returns does not keep predetermined items of medical history. [See 2.1.3]
Healthy Returns does not process medical histories. [See 2.1.3]
Healthy Returns does not identify proposed modes of treatment. [See 2.1.5]
Healthy Returns does not propose ancillary services. [See 2.1.7]
Healthy Returns does not provide ancillary services. [See 2.1.7]

2.5 Other Non Infringement Issues

2.5.1 Workflow

The Trigon system, comprising employees and computer systems, combines automated work with human intervention, decision making, and interaction in a traditional distributed data processing workflow architecture. The claims of the `105 patent represent a fully automated system with no intervening human interactions. Thus, the activities of the Defendants do not fall within the scope of the asserted claims.

2.5.2 Comprehensive Health Care Management System

The Trigon systems collectively form a reimbursement claims processing system and thus are only one component of a comprehensive health care management system as specified in the `105 patent.

2.5.3 Data Input Terminal

The Point of Care system uses a web-interface based on a modern computer-based desktop for data input at the provider's site. The provider computer used to accomplish the data input is not equivalent (not the same mechanism) as the point-of-sale terminal as described in the `105 patent.

2.5.4 Authentication

The Trigon system identifies a member but does not authenticate the member with any secret password or other technique.

2.5.5 Adjudication

The Trigon adjudication process is a judgment system and not a simple automated decision system. In adjudication systems a judgement is made based on the currently known information. This judgment can be later reviewed and overturned, changed, or left whole, as new information becomes available. This judgment can be appealed to a higher authority. The claimant and not the adjudication initiate the claim process.

The `105 patent claims describe a simple decision process of payment blocking. This is not equivalent to the more complex process of adjudication.

2.5.6 Multiple Payment Sources

The `105 patent describes a system where payment is blocked for a proposed treatment pending other actions. This approach assumes centralized control, consonant with the author of the `105 patent’s intention to have a single, integrated system. The Trigon

system operates in an environment where there are multiple payer sources. The two are not equivalent.

3. Definitions

We list here terms that have led to disagreements in the `105 claims chart constructions by plaintiff and defendant as well as terms that have been disputed in interpretation of the patent and the ensuing reports.

The definitions are introduced in a logical order and not in alphabetical order. For the readers' convenience we provide an alphabetical index. The index also lists some terms that are secondary elements in a primary definition, as `*Illness*' and `*Disease*' within `Diagnosis'. Definitions for some medical terms used in the report are provided in Appendix C.

- 3.16 Algorithmic systems
- 3.11 Ancillary Services
- 3.9 Case Manager
- 3.7 Chart Access
- 3.13 Comprehensive Health Care
- 3.12 Comprehensive Health Care System
- 3.10 Cost-effectiveness review
- 3.3 Diagnosis
- 3.3 Disease
- 3.4 DRG codes
- 3.18 Doc-in-a-box
- 3.11 Drug Cost-effectiveness Review
- 3.17 Expert System
- 3.21 Factor analysis
- 3.26 Health Risk Assessment (HRA)
- 3.3 Illness
- 3.22 Integrated Systems
- 3.14 Medical Director
- 3.7 Medical History
- 3.7 Patient Chart.
- 3.11 Pharmacy
- 3.7 Physical Profiles.
- 3.7 Physician's Chart.
- 3.25 Point-of-Sale Terminal
- 3.8 Reimbursement Claims History
- 3.26 RHA
- 3.19 Rule-based systems
- 3.6 Second Opinions
- 3.2 Sign
- 3.15 Smart System
- 3.1 Symptoms
- 3.20 Table
- 3.24 Terminal
- 3.5 Treatments

- 3.9 Utilization Review (UR)
- 3.23 Work Flow System

3.1 Symptoms

Symptoms are evidence of an abnormal state of one's health. Symptoms, if the patient deems them serious, are reported to a health care provider for a follow-up investigation. When patients describe symptoms, the physician to help arrive at a diagnosis (see Definition 3.3) will use them. Symptoms are rarely written down, although they may be noted in a problem statement for physicians that follow Larry Weed's methodology [BjornC:1970]. Occasionally symptoms are collected as free text. Physical observations, measurements, and laboratory tests provide further signs (see Definition 3.2) of normal or abnormal health. Perusing the patient's Medical History (see Definition 3.7) rounds out the material required to arrive at a diagnosis.

The definition of Symptom in the American Heritage Dictionary sense 2. [Heritage:2000] is "A sign or an indication of disorder or disease, especially when experienced by an individual as a change from normal function, sensation, or appearance."

The definition of Symptom in Stedman's Medical Dictionary [Stedman:2000] is "Any morbid phenomenon or departure from the normal in structure, function, or sensation, experienced by the patient and indicative of disease."

These definitions are consistent with our use of the term. These terms are not likely to have changed since 1990.

There are coding schemes available for symptoms: CMIT [Gordon:1971] and [RCGP:1974]. A symptom-oriented entry form, oriented towards physician use [SFT:2002] shows approximately 4000 candidate symptoms. Selecting the proper term for the variety of symptoms presented by a patient requires medical insight. Coding of symptoms can be useful for utilization review (see Definition 3.97.) since it allows matching patient's complaints with diagnoses and treatment. An earlier patent cited in ‘105 patent [Sinay 4290114 Sep., 1981] (see Section 5.17) developed its own coding scheme for symptoms presented in emergency care. Coding of symptoms is rarely performed in U.S. medical practice since the costs outweigh the benefits. Claims are not reimbursed on the mere basis of symptoms by TRIGON, the Federal government, nor by any insurance carrier we are aware of. We show examples of symptoms, taken from [Holland:2002], in Appendix B. A few diseases are **pathognomonic**, in that a single symptom determines the disease, for instance Koplik’s spots (on the buccal mucosa opposite the 1st and 2nd upper molars) are pathognomonic of measles (see Appendix C for its definition). Medical knowledge is still required in such case, since few patients will report that symptom, but rather complain of fatigue and rashes.

3.2 Sign

A Sign is an observation made by a health care worker or obtained from a clinical test to help determine a diagnosis. As such, signs complement the patient's reported symptoms.

The definition of Sign in The American Heritage Dictionary [Heritage:2000] is (8) “A body manifestation that serves to indicate the presence of malfunction of disease.”

The definition of Sign in Stedman's Medical Dictionary [Stedman:2000] is “Any abnormality indicative of disease, discoverable on examination of the patient; an objective indication of disease, in contrast to a symptom, which is a subjective indication of disease.”

These definitions are consistent with our use of the term. This term is not likely to have changed since 1990.

3.3 A Diagnosis

A Diagnosis is a specification of a ***disease***, i.e., an abnormality that causes abnormal signs and symptoms. Most diagnoses relate to multiple symptoms. Not all symptoms occur for given diagnoses. People with multiple diagnoses often show patterns of symptoms that differ from the sum of the patterns for each distinct diagnosis. The International Classification of Diseases (ICD-9) coding, used by the defendant and cited by the plaintiff has currently over 12,000 entries in its disease category.

The definition of Diagnosis in The American Heritage Dictionary [Heritage:2000] is "[a] The act or process of identifying or determining the nature and cause of a disease or injury through evaluation of patient history, examination, and review of laboratory data and [b] The opinion derived from such an evaluation."

The definition of Diagnosis in Stedman's Medical Dictionary [Stedman:2000] is "The determination of the nature of a disease, injury, or congenital defect."

These definitions are consistent with our use of the term. These terms are not likely to have changed since 1990.

Having an ***illness*** indicates a state of poor health. Being ill can be due to having one or multiple diseases, and for that reason is not a term used frequently in medicine.

The definition of Illness in The American Heritage Dictionary [Heritage:2000] is "1a. Poor health resulting from disease of body or mind; sickness. 1b. A disease. ".

Illness is not in Stedman [Stedman:2000].

The ‘105 patent generally uses the term ‘illness’ where medical specialists would use the term `disease'. The term disease is only used 3 times. When used in the `105 patent it is

unclear if a single disease, susceptible to a particular treatment, is intended, or if the holistic state of not being well is intended. We found no meaningful difference in the usage of the term, and hold them to be equivalent here.

3.4 DRG codes.

DRG codes. For governmental billing purposes (Medicare, etc.) the 12,000 ICD-9-CM codes have been grouped into 23 major diagnostic categories representing almost 500 individual Diagnostic-related Group (DRG) codes. DRG codes do not contain sufficient information to prescribe treatment. They do provide an indication of the range of effort required for treating a disease in an inpatient setting, and appropriate billing ranges. Because of their imprecision, they are used less than in the past but are still prevalent in many inpatient hospital environments.

3.5 Treatments

Treatments are the processes used to restore to a normal state. Their selection depend on the primary diagnosis, on other aspects of the patients health state, including concurrent diagnoses, and the utility that patient and doctor agree to a treatment when multiple treatments are possible, say medication versus surgery. The CPT coding used by the defendant and cited by the plaintiff has currently over 8,000 entries.

The definition of Treatment in The American Heritage Dictionary [Heritage:2000] is "(2a) an Administration or application of remedies to a patient or for a disease or injury; medicinal or surgical management; therapy. "

The definition of Treatment in Stedman's Medical Dictionary [Stedman:2000] is "A Medical or surgical management of a patient".

These definitions are consistent with our use of the term `Treatment'. The meaning of this term is not likely to have changed since 1990.

3.6 Second Opinions

Second Opinions are used when the patient or his/her surrogate wants to be assured that a treatment selected by a physician is indeed appropriate. Second opinions are valued when

i) a treatment has a high risk, as some surgeries,
ii) a treatment imposes much discomfort, say chemotherapy, or
iii) a treatment has a high cost.

Differences about treatment are often due to different value systems. For instance, a physician may seek a more promising treatment, but the patient has an aversion to risk or

pain. Sometimes patients have heard about costly or unusual treatments that the physician has rejected as having had little or no additional benefit over commonly accepted alternatives.

Some insurance plans will reimburse for second opinions in certain cases. Second opinions should be provided by an independent physician, not by medical directors at insurance companies.

The Blue Shield of California Handbook advises patients that "Second Opinions are helpful if you have any doubt that the proposed Surgery is the best option for your problem. Consider getting an opinion from a different type of doctor who treats similar Problems" [Kemper:1995]. More detail is provided in the exhibits in [Singer:1990] from *The Managed Health Care Handbook*, a guide for Health Maintenance Organizations (HMOs), page 381: [Mullahy:1996]

> Also used to determine a diagnosis, a second opinion exam is often performed to help clarify a complex medical outlook or to prepare alternatives to the current or proposed treatment. In group medical plans, a second opinion exam is sometimes required prior to certain surgical procedures that the carrier or the latest utilization review statistics show to have a high usage rate (such as hysterectomies, hip replacements, cardiac bypass, magnetic resonance imaging scans, disc surgery, etc.). Such exams are also called for when there is a conflict between potential treatment plans, when a questionable treatment is in place, or when the existing treatment plan is not achieving the expected outcome. The case manager who arranged for the second opinion exam is usually in attendance, and the physician conducting the exam often will become a treating physician.
>
> To get greater benefit from independent medical exam and second opinion exams, a case manager should thoroughly understand the purpose of any exam ordered and be specific about what the physician's report should address. The examining physician should be given as much information as possible (operative reports, diagnostic test reports, X-rays, computed tomography [CT] scans, etc.) and be given enough time to review all the data prior to the actual exam. After reviewing the physician's report to confirm that it is responsive to the initial request for information, the case manager should speak to the physician about unanswered issues.

We see here that getting second opinions requires clinical expertise and records, and involves the patient, multiple physicians, and, if the setting is an HMO, a ***case manager*** able to monitor the patients' progress.

3.7 The Medical History

The Medical Record, in private practice often referred to as the ***Patient Chart***, is the collection of all past medical events, treated as an inpatient or as an outpatient in any

setting or location, insured or not, for an individual. This chart is also referred to as the ***Physician's Chart***, emphasizing its location. It is an important information source for establishing diagnoses and selecting a beneficial treatment. It should include problems and symptoms presented by the patient, tests made and signs obtained, diagnoses, treatments ordered, prognoses made and results achieved (see [Weed:1981], [Weed:1985], and [Shortliffe:1990]).Since the medical record includes historical data, it is sometimes called the medical history. We follow Holland's [Holland: 2002] example and quote [Noble:2001]:

> Perhaps the most central part of any medical database involves the collection of information regarding previous medical diagnoses, their treatment and response to treatment, current and previous medications and allergies, history of immunizations and childhood illnesses, and prior surgical history including response to anesthesia. This is generally accomplished through patient interview, through review of immediately available medical records, and by formally requesting medical records from previous providers or hospitals at which the patient was treated. The information obtained should be recorded on a problem list, which is generally organized into active and inactive problems, and prominently located in the patient's office chart.

Singer [Singer:1990, p.27] also stresses the importance of comprehensive contents in his definition of Medical History. He does not include Symptoms however.

A ***physical profile*** is an optional but useful abstraction of the current state of health of a patient and complements the medical record. The ARAMIS system, used in Immunology clinics, focuses on a time-oriented sequence of Physical Profiles [Wiederhold:1975]. Each snapshot includes specific diagnoses of current problems, subjective observations, signs from clinical tests results, and treatments prescribed, for a total of about 330 values. Some `105 patent claims require Physical profiles, but the accused system, Trigon, collects only diagnoses and treatment data submitted for reimbursement.

The `105 patent places ***chart access*** (`105 in Fig.5) in the physician's office, presumably in the `Physician file' (44 in Figures 1 and 3). Because of confidentiality concerns the patient's medical history is best kept within the physician's computers, but the `105 is inconsistent about its location (see Section 1.4), often confusing it with the collection of elements reported for claims reimbursement (see Definition 3.8).

An ideal, comprehensive medical record is hard to achieve since the information is created at many points in the healthcare system. It has not been achieved in any systems prior to the patent, nor has it been achieved now. Singer criticizes potential prior art, brought forward by earlier defendant's, for not having long-term laboratory results available as part of such a history (see Section 5.3). The `105 patent makes no contribution towards achieving a comprehensive medical history. Instead it confuses the experts (see Section 1.4).

3.8 The Reimbursement Claims History

The Reimbursement Claims History is the collection of billing events that an insurance carrier can collect. Depending on the comprehensiveness of the coverage, more or fewer events will be collected. The data collected is limited to the reimbursement claims justification. The problems that a patient presents, the response to treatments, allergies, details of hospitalizations, including medications and routine treatments given there, over-the-counter medications, and social and financial history elements are not available. There are also legal limitations on the time that reimbursement claims records may be kept, typically 7 years. Childhood events and immunizations are not available for adults. Reimbursement claims paid by other insurance carriers are also not available. In order to get a broader view of reimbursement claims histories, some companies provide integration over multiple insurance carriers [VantageMed:2002]. The Medical Insurance bureau aggregates information for the industry, but limits its classifications to 230 items, including non-medical observations [MIB:2002]. While an insurance reimbursement claim history is a subset of a medical history, it cannot replace the medical history for making treatment decisions. It is important for insurance companies to spot cases of individual, provider, and group over utilization as well as outright fraud. Actuaries to determine health plan rates to be set for future contracts will also use it.

3.9 Utilization Review

We will use in our report the definition of Utilization Review in [Shortliffe:1990]: "In a hospital, inspection of patients' medical records to identify cases of inappropriate care, including excessive or insufficient use of resources." Utilization reviews are carried out by quality review boards, focusing on cases that are reported to them, or selected as being inadequate or excessive. Utilization review has become important in the last 20 years, as more health care is being delivered on a capitated basis, to assure that adequate care is being delivered where there is no incremental financial incentive to provide such care.

From Allcare's claims chart: "The evaluation of medical necessity, and efficiency or quality of health care services, either prospectively, concurrently, or retrospectively." That definition matches [Cummings:2002, p.85-86]

From Trigon's claims chart: "cost effectiveness." Because of the gap in definitions we will define another term that matches Trigon's definition of Utilization Review, a definition which stems from its business, being an insurance carrier and not a quality review board.

As Holland acknowledged in his deposition [Holland:2002D], the term utilization review has different interpretations depending on which organizational unit is involved..

> Q. And did that smart claims payment system perform utilization review?

A. It performed a form of utilization review. To a claims manager, what it did, i.e. claim edits that were attempting to look for inappropriate care, inappropriate claims, redundant claims, that is a form of utilization review in a claims environment. But a medical manager, i.e., a physician, a medical director or a nurse working in the medical management department of health care, of a healthcare, health plan, would not consider that utilization review, so you have to understand that terms were used interchangeably and some were embraced by different departments.
[Holland:2002D, p. 101 l. 21-22, p. 102 l. 1-22].

Singer [Singer:2000, p. 61], being a specialist in this area, points out the proper distinction between utilization review and pre-authorization of treatments.

3.10 Cost-effectiveness review

We define **Cost-effectiveness review** to be a process that, typically a priori, reviews expected expenditures for treatment and determines if the medical condition warrants the treatment expenditure. Cost-effectiveness review may disallow reimbursement for costly alternatives or deny treatment reimbursement altogether. The patient or the provider may appeal such decisions or decide to proceed with the treatment without insurance coverage. Note that cost-effectiveness review, carried out by insurance carriers, can easily be in direct conflict with utilization review (see Definition 3.9)

The cost-effectiveness review process, is referred to in the Allcare documents also as Utilization Review, in the sense of review of treatments ordered for medical effectiveness at the given cost. As such, it is a health-care reimbursement-oriented subset of Utilization review, focusing only on denial of treatments and not considering changes or augmentation of treatments.

Cost-effectiveness review is related to **cost-benefit review**. In performing cost-benefit reviews, the assumption is that all factors can be reduced to monetary terms, i.e., dollar amounts. In health care delivery, patient welfare is a concern that cannot be reduced to monetary values, and medical knowledge is needed.

3.11 Drug Cost-effectiveness Review

Drug Cost-effectiveness Review is a subset of Cost effectiveness review (q.v.). Medical practice allows the substitution of equivalents of prescribed medications by a ***pharmacy***, unless the physician has indicated that no substitution is permissible. Performing this function is generally subcontracted to specialized organizations that interact with the pharmacies frequented by the patients. In the patent no explicit mention has been made of pharmacy services, but the term ***ancillary services*** is used frequently. Experts opining for the plaintiff have included pharmacy services within ancillary services. That is not our definition of the term, but we won't quibble. Well known

ancillary services are laboratories, providing quantitative signs (q.v.) to help in diagnoses, X-ray and other scanning modalities, Physical Therapy, Physical Rehabilitation, Radiation treatment, and an ever-broadening range of medical technologies.

In the case of prescribed medications, cost-effectiveness review may direct generic substitution for prescribed compounds. Medication review is performed outside of the Trigon systems at Medco, following published guidelines. Trigon systems do allow retrospective analyses of medication expenses for patient groups.

3.12 Comprehensive Health Care System

A comprehensive information system should include all the information processing components needed in a discipline. We use the common meaning of "including much, of large content or scope" [OED:2002] for the term comprehensive, and when we apply it to health care systems there is no doubt that the vision in `105 specifications is indeed of a `Comprehensive Health Care System', in fact so much so that is quite beyond our -- and that includes our government's -- ability to implement it all. We can refer to such a system as a ***Health-care Vision***.

Because of the breadth of that vision, the use of the term `Comprehensive Health Care System' leads to disagreement here. It is used in more than one sense in the `105 patent. Because of this we find that the patent does not establish an adequate basis to give notice of the metes and bounds of the term. Furthermore, the patent holder uses the term `Comprehensive' to apply to his vision of health care [Cummings:2002]. We will define that term as well in Section 3.13..

The preambles of asserted claims 1,4, 16, 19, 34, as well as claims 31,32,33 of the `105 patent all recite a comprehensive health care system, although the actual body of the '105 claims recite a very small subset of the system described in the specification. For instance, claim 1 is limited to entry of a patient identifier and the patient's symptoms, having the means of payment known, providing suggestions on treatment, and indicating those treatments for which payment is to be prevented. Such a system is merely a ***Health-care Payment Control System Based on Symptoms (with automated treatment proposals).***

Note that the systems provided by Trigon are a ***Health-care Payment System Based on Diagnoses.*** They differ from the claimed ***Health-care Payment System Based on Symptoms*** at least in the input they require. But, because of that difference, they differ drastically in methods and technology - and must differ, since the claimed systems cannot be built with today's technology, due to the discontinuity elaborated in Section 1.1**.**

3.13 Comprehensive Health Care

A social organization to provide Comprehensive Health Care is a vision of many leaders in health care and refers to the gamut of health services, including preventive care, curative care, and rehabilitation [Kostrzewski:1976]. The author of the patent has focused throughout his career on preventive care, leading to wellness. The curative aspects deal with illnesses (see Definition in Section 3.3) and include emergency and long term care. For our aged we must also include palliative care. In the sense that health care should deal with all aspects of our body and our psyche, comprehensive care is also referred to as holistic care. This spectrum of care is delivered by a wide array of services for the well, during maternity, for ambulatory outpatients, for hospital inpatients, and for the aged. Comprehensive health care must also be delivered affordably and consistently to all economic strata by a wide variety of health care providers and institutions [Kellogg:1999]. This goal cannot be achieved merely by having a Comprehensive Health Care System in the sense of definition 3.12, but requires societal commitments beyond what seems to be affordable.

Unfortunately, the term "Comprehensive Health Care" is also an attractive advertising term, and as such used by many organizations in the field, all different, often modest, to describe their offerings.

3.14 A Medical Director

A Medical Director is a certified M.D. employed by an insurance carrier or provides service to an insurance carrier, such as Trigon, to establish the medical necessity of treatments. Such services are required when the decision to disallow reimbursement, either prior to the treatment or subsequently in a reimbursement claim cannot be based on administrative rules, as not being a member of the health plan or not being covered by the plan for specific diagnoses or services, say, psychiatric care. In addition to reimbursement claims data (diagnostic code, requested treatment, a brief optional note), the medical director can access the local reimbursement claims history for the patient. If more medical information is needed the Medical Director contacts the patient's physician office by telephone to discuss the case with the health care provider.

3.15 Smart System

Smart System is not a well-defined term in Computer Science. Informally, a smart system is a computer system that is able to make decisions or suggest actions using reasoning that are not immediately obvious to the beholder. Such a definition of course depends on the competence of the beholder. The complement to such smart systems are algorithmic systems (see Definition 3.16), systems whose behavior can be predicted.

In the 2000 deposition an attempt was made to arrive at a definition through the following interchange [Cummings I: 2000, pp. 161 l. 23-25, 162 l. 1-14]

> Q: `So the system of Claim 1 is a smart system, correct?'

A: `It's part of the utilization. Right'.
Q: `Is the answer yes?'
A: `yes',
Q: `What is a smart system?'
A: A smart system is capable of managed artificial intelligence or rules based'.
Q: `What is artificial intelligence?'
A: `Pattern analysis'.
Q: `Okay. What is Pattern analysis?'
A: `The ability to keep a system learning as you add more data'.

While we would not consider Pattern Analysis an Artificial Intelligence system, we do agree that a system that keeps learning as more data is added does fall into that category.

Kaliski, in his deposition [Kaliski:2002D, p. 38], argues that even a system employing simple business rules is smart:

> Likewise, CHIPS and AMISYS are rules-based applications for determining whether to pay, deny or pend incoming reimbursement claims based upon a review of the content of the [reimbursement] claims themselves. (Felts deposition, pp. 15-19, discussing the business rules used therein).

The reimbursement claims contain the patient's health care plan membership identification, their diagnoses, and proposed or performed treatments. The business rules will deny payment to non-members, for non-insured diagnoses, and for certain treatments - absolutely or based on the diagnosis. If the situation is not covered by the simple algorithmic rules, as when a patient has multiple diagnoses, it is forwarded to the Trimed component (see Section 2.2.2.6) for manual processing. Is a system that handles the filtering and only simple cases smart? To a scientist, and I expect that this would include Prof. Kaliski and most educated observers, such a system falls into the algorithmic category, since the results of the computation are quite predictable. Prof. Kaliski's definition is flawed as applied to the technology of the '105 patent because, according to his definition, all computerized systems are smart systems. Such a definition fails to give any meaning to "smart" and as such is not a meaningful definition.

The Trigon systems are certainly less smart than a system envisaged by the `105 patent applicant, which:

> In accordance with the "Smart system" characteristics of the invention, Physician File 44 preferably will include an identification of the most commonly encountered diseases and other ailments, together with symptoms usually associated therewith. Accordingly, if symptoms are entered into the system terminal (e.g., one of terminals 11a-11c), and an identification of the corresponding illness is requested from the Processing System 10, the physician's file is interrogated, and the system prepares a list of the most likely medical condition corresponding to such symptoms, together with the generally approved and/or recommended treatment protocols.

As discussed in Section 1.1, we do not know now how to build such a smart system today. Any beholder would indeed consider a system smart that could recommend treatment from symptoms without further tests providing signs (see Definition 3.2) , without the patient's medical history (See Definition 3.7). While the `105 patent's specification only generates a list to reduce the physician's work to selecting choices, the patent `105 claims fail to provide for the needed physician interaction.

Unfortunately, the `105 patent does not and cannot teach us how to build such a smart system.

3.16 Algorithmic Systems

Algorithmic systems use predetermined procedures to arrive at a result. As such, their results are perfectly predictable. Most usage of computers is for algorithmic systems, and systems that approve payment must be, because if a question arises an explanation is required. We quote an entry from the [OED:2002]:

> Algorithm 3. Med. A step-by-step procedure for reaching a clinical decision or diagnosis often set out in the form of a flow chart, in which the answer to each question determines the next question to be asked.

> Algorithmic systems have been developed that aid a physician in refining a diagnosis:
> Flow-charts, diagnostic keys and algorithms in the diagnosis of dysphasia. [Lusted:1970]

Flowcharts, a pictorial presentation of algorithms, are also available in self-help books that provide guidance to people that wish to decide what to do in case of illness, e.g., [VickeryF:1989]. These books also stress when their algorithmic procedures fail and a doctor should be consulted.

3.17 An Expert System

An Expert System is an interactive computer program that helps users with problems that would otherwise require the assistance of human experts; a program that presents the computer as an expert on a particular topic. Expert systems capture knowledge in rules that can be communicated to others as advice or solutions.

> "The programs often simulate the reasoning process used by experts in certain well-defined fields." [Websters:1994].

The capabilities of such expert systems are limited to `well-defined topics', and not capable of the breadth envisioned in the `105 specifications [Buchanan:1985]. The term is only used once in the `105 specification (see Section 1.6).

Expert systems are one topic in the field of **Artificial Intelligence [**AIM:1977]. Other topics in this field include speech recognition, image recognition, inference, abduction, deduction, and machine learning, i.e., in general computational methods that require a layer of explicit and manipulable knowledge about tasks that are to be performed [Davis:1982]. In the context of the `105 patent, such knowledge might include a model of human metabolisms, connecting the etiology of diseases to possible external manifestations. Unfortunately we are just in the beginning of understanding metabolic interactions. The `105 patent does not contribute to our knowledge, nor teaches us how to acquire such knowledge.

3.18 Doc-in-a-Box

Doc-in-a-box is an informal term that denotes an Expert system (q.v.) that performs some of the functions that one expects a clinician to be able to perform [Holland:2002D, p. 151 l. 11]. In practice the tasks performed automatically are small subsets of a clinician's capability, for instance selecting and ranking relevant treatments for a known diagnosis. The most common technology used is Rule-based Systems (q.v.), but some Doc-in-the-box program have used computational, i.e., algorithmic (q.v.) approaches, as in [Bleich:1969].

3.19 Rule-Based Systems

Rule-based systems are a technology for expert systems (q.v.) where the experience of experts, in our case typically physicians, is encoded in If-*a*-then-*b* rules. The '*a*' term can combine multiple factors, as data or the results '*b*' of prior rules. In Section 4 we cite some such systems, for instance Mycin [Shortliffe:1976]. When the number of rules grows large, say more than 50, the result becomes hard to predict, even for the author of the software. Such systems indeed become `smart systems' by our definition. To cope with the unpredictability, smart systems, such as Mycin have been equipped with ancillary programs that provide an explanation service [Davis:1982].

Unfortunately, medicine is to complex to allow us to build rule systems that could bridge the gap from general symptoms to treatment. For instance:

> "MYCIN was one of the first systems dealing with this issue, although the system was actually restricted to the clinical areas of sepsis and meningitis" (see Section 4.6.4) [LucasBSH:2000].

Rule-based systems have not grown beyond a few hundred non-grounded rules. Grounded rules are just a way of entering data into rule-based systems. The complexity

of interactions among hundreds of rules is such that adding subsequent rules and testing their effect becomes an impossible task. Rule-based systems, or production systems using an earlier convention, are described in [Barr:1989].

The definition given in [Barr:1989] is operational:
A rule-based system is a system that

a. reasons with domain-specific knowledge that is symbolic as well as numerical
b. uses domain-specific methods that are heuristic (plausible) as well as followings procedures that are algorithmic (certain)
c. performs well in its problem area
d. explains or makes understandable both what it knows and the reasons for its answers
e. retains flexibility.

The systems used at Trigon do not carry out:

a.) reasoning in the sense of [Barr:1989],
b.) do not use heuristics, and
c.) do not explain what they know.

3.20 A Table

A Table, as used in Computer Science, is "an arrangement of numbers, words, or items of any kind, in a definite and compact form, so as to exhibit some set of facts or relations in a distinct and comprehensive way, for convenience of study, reference, or calculation. Now chiefly applied to an arrangement in columns and lines occupying a single page or sheet, as the multiplication table, tables of weights and measures, a table of logarithms, astronomical tables, insurance tables, time-tables, etc. But a table is sometimes merely: 'An orderly arrangement of particulars, a list.'" [OED:2002].

The orderliness characteristic of a table inhibits its use in supporting medical decision-making. The symptoms presented by a patient are not orderly, are incomplete, and overlap. The regularity of a table is also inefficient in situations that are as complex as health care tasks. Even the treatments that are candidates, once a diagnosis has been made vary in applicability, in number, in length, and in availability. Tables will be found in simple situations, say where a treatment is associated with a price, member identification is listed with the plan, or where a physician code can provide the provider's name and address. Tables are not considered instances of `smart systems'.

3.21 Factor Analysis

Factor analysis is a well-known statistical technique that analyzes effects due to multiple causes. While simpler analyses focus on one factor at a time, keeping all other factors constant. If there are more than 10 factors, the single factor approach soon becomes unwieldy. In health care, there are typically many factors. Factor analysis

processes observations from past experiments using models describing causes and effects in order to produce multiple factors that can be used to predict effects in future situations that are describable by the same factors [Snedecor:1967]. Factor analysis has been widely used in agriculture, where there is a single outcome, namely the yield of corn in a controlled plot of land. Once the best combination of factors, as planting time, fertilizer, and irrigation is known, the results can be used in future plantings. In the examples cited by Cummings in his depositions, a Health Risk Assessment (HRA), there may be as many as 20 candidate factors and one outcome, perhaps the patients' blood pressure. Such a study will require many hundreds of cases. Since 'wellness', rather than management of disease has been the primary interest of the patent holder, he uses his experience with Health Risk Assessments (HRA) as a model for disease management in a Comprehensive Health Care System. Giving advice on managing wellness does not involve making diagnosis, and does not require the medical certification required for diagnosing and treating diseases. Only a modest number of factors are involved, focusing on diet, smoking, drinking, exercise, and sometimes workplace related risks.

If the effects are not linear combinations of the causing factors, as is often the case in health where large amounts of, say a drug, have disproportional large effects because of inability of the human metabolism to excrete excess products, many more observations are required. If factors interact, as say smoking and exercise, still more data is required in order to extract the interaction effects. Note that 20 factors could have 380 simple interactions. An HRA study typically cannot afford to look at the actual desired effect, namely patient survival, and may use a surrogate as low blood pressure. Since significant healthcare effects are often delayed, studies into actual disease outcomes have to collect data over long periods of time. The premier HRA study is the Framingham study to elucidate factors leading to heart disease [Framingham:2001]. Here over 5000 patients have been followed about 50 years and over additional 5000 patients representing offspring of the original patients have been followed for 30 years. Only a few global studies of this type exist, partially because of cost, partially because other diseases have lower incidences, so that we cannot collect large enough populations for trustworthy analyses.

A great deal of uncertainty remains in health care outcomes, even in simple studies, due to an inability to consider all factors. For instance, only a few genetic factors can be obtained today, while we estimate that there are about 35,000 genes controlling many of our functions, with yet an unknown number of promoters and inhibitors. In the absence of factors, many more patients must be randomly selected for health care studies in order to even out the effect of such natural variances.

In summary, the effect of the limits of purely statistical analysis to drive health care prediction, and the amount of data required to analyze the relationships of several thousand interacting symptoms to hundreds of treatments, exceeds by far the population of the world. Medical science and education provides an understanding of the processes and the mechanisms, so that human intelligence and experience can largely overcome the inadequacies of global, formal statistical techniques.

Factor analysis remains a useful tool to analyze disease models that are well understood. The remaining uncertainty can be tolerated when the actions to be taken are not life threatening -- as in reducing Health Risks or if they are simply advice to a physician. Factor analysis falls far short of providing the information that a general smart system, as hypothesized in the Cummings deposition [Cummings II:2000 p.206 p. 207 p. 208 l. 4-7], would need.

In [Cummings:2002] the magnitude of the problem becomes clear. Performing a factor analysis for a marketing study with 345 factors and 144 variables was a major task, performing a factor analysis for 12,000 diagnoses and 7,000 symptoms dealing with millions of patients over decades is a task many more orders of magnitude of complexity. The limits of available programs in that period was f factors and y variables [BMD:1979].
<<work this out>>

3.22 Integrated Systems.

We define an Integrated system as one where each participating component can share data electronically with other components, continuously or at an adequate schedule. This definition is generous and allows multiple sites, multiple networks, multiple communication standards, multiple vendors, multiple owners, multiple types of computers, multiple operating systems, and multiple computer languages to be used. Limiting the extent of multiplicity will reduce confusion and costs, but does not affect the principle. Removing all the multiples, i.e., placing it all on one computer is the ultimate integration, but only feasible when the totality is modest.

In practice, the scope of integration for computer systems varies greatly and has changed over time. My research in the 70's and early 80's dealt with integration of data from many sources into one coherent database, leading to tightly coupled systems. As communication improved the need to tightly integrate systems lessened, and most systems became loosely integrated, often managed and owned by distinct entities. Such systems can be much larger and support the vision of the `105 patent. Since it integrates needs of patients, healthcare providers, insurance companies, employers, and financial institutions, it is of necessity loosely coupled. Not mentioned, but crucial, is the role of the federal government, both as a supplier of reimbursements (Medicare), funding (Grants to hospitals and health care researchers), operator of hospitals (the Veterans Administration and Department of Defense) and consumer (see the FEP module in TRIGON, for instance, described in Section 2.2.2.7).

Formal definitions do not help much in this field, in part because the concept keeps changing with the progress in computing and communication. For instance:

- "Integrate: The process of putting various components together to form a harmonious computer system." [Webster:1988. 1994] Harmonious is not defined.

- "Integration: The combining of diverse elements of hardware and software often acquired from different vendors, into a unified system. [Webster:1994], but later editions give up and fail to define this or related terms [Websters:2000].

3.23 Work Flow System

A processing system that combines automated processing with manual human interventions.

The partial automation of a process, during which information or jobs are passed from one human to another for action, according to a set of procedural rules.

3.24 Terminal

The definition of Terminal in the American Heritage Dictionary sense 5. [Heritage:2000] is "A device, often equipped with a keyboard and a video display, through which data or information can be entered or displayed."

A smart terminal would include significant computational capabilities while a dumb terminal would have very limited computational capabilities.

3.25 Point-of-Sale Terminal

The definition of Point-of-Sale in the American Heritage Dictionary [Heritage:2000] is "A business or place where a product or service can be purchased."

A Point-of-Sale (POS) terminal may include bar-code readers, credit card swipe capability, a phone interface, cash register functionality, and specialized keys mapped to specialized functions.

3.26 Health Risk Assessment (HRA)

The Rippe Health Assessment (RHA), called the Health Risk System by Cummings, is based on a philosophy involving five pillars for comprehensive health evaluation. Every RHA client receives comprehensive evaluations in each of these five important areas: (Based on Dr. Ripple book "Lifestyle Medicine" published in September 1999).

- Comprehensive Medical History, Physical Examination, and Laboratory Work: Every client of the Rippe Health Assessment receives a comprehensive health history as well as a physical examination performed using protocols developed by Dr. Rippe. In

addition, complete laboratory work, including a variety of sub-specialty tests and procedures using state-of-the-art medical technologies and equipment are available.

- Optimal Nutrition: Optimal nutrition is a key to good health. The Rippe Health Assessment nutrition team provides a comprehensive in-depth nutritional evaluation to all RHA clients along with recommendations for change.
- Physical Activity/Exercise: An active lifestyle is a healthy lifestyle. Dr. Rippe is a co-author of the guidelines developed by the Centers for disease Control and the American College of Sports Medicine on physical activity for adults. An RHA Exercise Physiologist provides an in-depth assessment of physical activity and exercise followed by a personalized program tailored to the individual's needs, interests and current fitness level.
- Personal Vitality: Vitality is much more than just physical well being and freedom from disease; it is also spiritual, emotional and social health. The RHA vitality staff provides in-depth analysis and counseling to provide every RHA client with guidelines to achieve optimal vitality.
- Pharmacy Evaluation: Often, interactions between medications, supplements, vitamins and minerals represent an area of great confusion for individuals. The RHA/PharmaCare pharmacy staff provides a comprehensive pharmacy assessment to address these important concerns.

4. Pre-1990 State of the Art in Health Care System

We start with a general introduction. We then examine the limitations and asserted claims using Allcare's claim construction chart in Section 4.2.
We then list on Section 4.3 general references that provided overviews of prior art.
In Section 4.4 we list specific health care systems that must be considered prior art by the broader interpretation of the patent. In Section 4.5 we describe some relevant health care reimbursement systems, since these are congruent with the objectives of the `105 patent claim and the services provided by the accused. In Section 4.6 we list and briefly describe some specific technologies that are cited in the patent or by experts as representing prior art. Through out Sections 4.3 to Sections 4.6, several key systems are compared to the asserted claims. This section concludes with a summary.

Brief descriptions of the patents actually cited as prior art that were cited in the patent application are provided in Sections 5.10 to 5.17.

4.1 The Failure to Present Relevant Prior Art.

We start by presenting certain inconsistent testimony offered by Allcare's witnesses, the applicant (Cummings), and Charles Singer, a consultant to Allcare. Singer assumed that for the patent to be valid it required full automation, since the health care processes described in the patent had been ongoing with manual paper-processing for ages, and since the middle 1960's with increasing levels of automation.

We now cite the testimonies that have led us to this conclusion, first Cummings, then Conner, and finally Singer:

> Q: (Patent office) "just did searches of patents, did not do searches of what vendor systems there were or what other hospitals were doing, what insurance companies were doing, did they?
> A. My background and assumption on that was Bill (Conner) was with the managed care side.
> Q. So you were relying on Bill Conner for the expertise to determine whether or not this was novel; is that correct?
> A: I was relying upon Bill and the way he worked with the patent attorneys with John and Andy to do that and when Bill asked for a search to be done, I assumed it was a literature search, because a couple of searches were done. So I assumed it included the literature as well. But Bill's knowledge of the HMO systems and so forth was far – he had been in the business, so his knowledge of that and the technology people he had and, you know, the fact that he had brought in a guy from, you know, the Tandy organization and his relationship with that and American Airlines and those folks, that's really where I saw the contribution and the expertise that I relied on. [Cummings VI 2000, p.130. l. 2-24]

A. Yes. I basically put this under John's leadership, worked with him on it. He had the power of attorney. He worked with me for that disclosure. And when you looked at this particular document, to me it was a subset of what we were already doing and what we had already declared was out there. And we didn't -- we were not saying medical payments was a part of the process that was key. It was the managing of the care, and managing the care was really the key.
Q. So you're saying it was out of your hands, you gave it over to Bill Conner?
A. I gave it to Bill as my responsibility, so I viewed my responsibility as to get it into Bill's hands. When I saw Bill had referenced going over BankOne material, I assumed that Andy had seen that and the question to me is basically, you know, has -- have I gotten it into Bill's hands, and have I done my responsibility? And that was my responsibility to do that.
Q. You feel like you fulfilled your responsibility to Bill Conner?
A. I feel like I fulfilled my responsibility to the process of putting the patent application in place.
Q. But you didn't follow through and make sure that the patent examiner had the BankOne disclosure?
A. The logic that I had relative to the BankOne disclosure was, we've seen these disclosures and here is where BankOne was not a substantive difference from this particular disclosure.
Q. So you're saying that you didn't think it was material and didn't need to be provided to the patent office?
A. Well, I'm basically saying I thought the information had gotten to John, and John had made a judgment relative to the information as he reviewed all the relevant material.
Q. Do you think sitting here now that it should have been provided to the patent office?
A. I don't, basically because I don't see it as having substantive difference other than just a payment system. It's a generic credit card transaction system turned towards the payers. You're just sliding in different people instead of retailers or others. It's not a system that in itself really is anything more than a payment system.
Q. Even though the system includes a point of sale terminal at a provider office, a connection to insurance company, connection to an employer, a connection to a patient's checking account or credit card, connection to drug companies, et cetera?
A. That's all payment. I mean, the definition of the system is that it's a payment system. [Cummings:2002, p. 124 l. 19-25, p. 125 l. 1-25, p,126 l. 1-12]

Charles Singer was retained by Allcare in 1990 to investigate the position of the `105 patent with respect to the state of the health care industry.

"A: I don't remember any report in writing. He verbally said that he looked in all of the places that he felt, at the beginning of our relationship. such prior art might exist, if it did, and was satisfied that it didn't" [Conner II:2000, p. 35]

His earlier publication documents his knowledge of the health care industry. [The Singer reports]. We can assume that he was familiar with many, if not all of the systems cited in Section 4 of this report. For preparing his reports, he would also be comfortable in performing literature reviews which document these and other entries in this chapter.

The report Singer prepared for Allcare states:

> that, by law, an issued patent is presumed valid" [Singer:2000, p.6].
> For the description of the patent Singer relies on the preferred embodiment:
> p 140 "to be honest with you, I looked at the claims probably spent – those charts, and probably spent 5 to 10 minutes on them, and then decided that I would prefer the language of the patent directly. I found the charts sometimes a bit confusing, harder to read, than just reading it directly. [Singer:2000, p.140 l. 3-9]

quoting,

> the `105 patent specifically states that `The preferred embodiment of the present invention includes integrated connection and interaction of the patient, healthcare provider, bank and other financial institution, utilization review, case manager ... [Singer:2000, p.11]

Inadequate automation causes, for instance, Singer to dismiss the Optimed system:

> In the OPTIMED system described and documented by Mr. Weelman, it is clear that the input terminal is housed at the utilization review organization or the insurance company. Furthermore the described communication link between the physician's office and the UR staff is not a computerized data link, but rather the then traditional (and inefficient) phone call that the `105 patent means to eliminate [Singer:2000, p.11].

Singer also values the term `comprehensive' used in the `105 patent as having to include all functions cited, even tough the claims are much narrower. For instance, he fails the HELP system of the LDS hospitals for not having a long-term patient record:

> .. a comprehensive system as described in the `105 patent is dependent on a comprehensive longitudinal patient history, with information being retained for significantly longer periods of time, if not over the patient's lifetime. [Singer:2000, p. 9]

The `105 claims have no such requirement, and in fact seem only to collect symptom and treatment codes. Neither does the accused system maintain such desirable longitudinal records.

We see that the applicant and the person who investigated prior art for that patent hold opposing views of what the patent means.

If we were to allow the construction advocated by the patent holder and Allcare, and allow, for instance, that

- a comprehensive system does not have to be all inclusive
- any computation can be a smart system
- that the required terminal hardware can be placed wherever needed, even if not specified
- the process can include a mixture of automated and manual steps,

then, systems as described below in Section 4.3 and 4.5, with their accompanying support environment will invalidate the `105 patent in whole or in parts.

The plaintiff cannot have it both ways:

1. ***reject prior art as not providing comprehensive and integrated full automation as stated in the `105 vision***
2. ***seek license fees and/or damages from current systems that do not provide comprehensive and integrated full automation.***

A particularly pernicious example is that any system that does not provide both inpatient and outpatient services is not regarded as being prior art, since the `105 patent specifies its integration. But the plaintiff is willing to extract license fees from systems that have disjoint processing of such data. In practice, the information system demands of inpatient (intense, rapid response, high cost) differ greatly from outpatient operations (voluminous, long term, modest costs). Every health care manager would prefer the integration, but technical difficulties have prevented it in most places, including at Celebration Hospital, the model institution associated with Disney's technology demonstrations where Cummings is a council member, executive vice-president, and fund-raiser.

> "... And those ranges from our historic involvement with the hospital at the new Disney City called Celebration where we brought that on-line through the visioning. [Cummings:2002, p. 12. l. 16-18]
> A. So we advance through either capital campaigns or through particular annual giving campaigns or special events the opportunity to get people a chance to invest their philanthropic dollars in building health care in Orlando.
> Q. So it's fund-raising and then distribution of funds for the purpose?
> Q. You said that you also sit on the president's council for Adventist Hospitals?
> A. Yes. [ibid, p13. l.11 -- p14 l.1]
> ... I believe you testified that you're the executive vice president for Florida Adventist?
> A. Right, for the Florida Division of the Adventist Health System. [ibid p.14, l. 16-l20
> We were talking about the level of integration of the systems at the Florida Hospital. I believe that you testified that they were not integrated to the extent that you would like to see them integrated.
> A. Yes.

> Q. Is that correct? Is there any reason why they're not as integrated as you would like?
> A. Sure. The health care industry in general is not integrated. It's behind. Florida Hospital is probably on the leading 25 percent of that integration, but the health care industry by and large has a tremendous I.S. -- underlying I.S. issue. We just don't have the ability to integrate all the data, unlike many other industries. It's been a universal criticism and cry of the presidents of the institutes of medicine to others saying we've got to change the I.S. system. We've got to have an investment in I.S., something like Hill Burton was to invest in infrastructure into the bricks and mortar. [ibid. p. 67, l. 1-17]

Everywhere vision differs from practice, even at leading institutions.

We now proceed with the specifics.

4.2 Claim Construction with their Limitations

Using Allcare's claims construction chart, the asserted claims of the `105 patent are construed by first building limitations, which are then assembled into claims. The constructed limitations and asserted claims of the `105 patent (CCL) are then compared to the features of the systems included in this section.

4.2.1 Claim Limitations.

- **[CCL-Preamble]** The preamble is not a limitation.
- **[CCL-Input Means]** A physician office terminal.
- **[CCL-Patient ID]** Information identifying one of two or more persons identified in advance.
- **[CCL-DB-Treatments-UR]** Database of elected procedures identified for utilization review [The evaluation of medical necessity, and efficiency or quality of health care services, either prospectively, concurrently or retrospectively. Examples of criteria for utilization review cited within the patent include "any of a variety of factors for review such as Cost, Treatment Results, Referral Matters, Other Opinions, and the like."].
- **[CCL-Payment Means]** 1. Medical payment system or 2. Computer system which performs an adjudication procedure and electronic payment or 3. Computer system programmed to perform automated funds transfer.
- **[CCL-Symptoms]** Information relating to or representing a sign or an indication of disorder or disease, especially when experienced by an individual as a change from normal function, sensation, or appearance.
- **[CCL-Proposed Treatments]** 1. Smart System that proposes mode of treatment or 2. Computer system that accesses patterns of treatment protocols to determine whether the treatment is appropriate or 3. Computer system that permits the user to enter a proposed mode of treatment.
- **[CCL-Indicia]** 1. A conventional printer capable of printing out reports in hard copy form or 2. A monitor screen for displaying visual display or review of data.
- **[CCL-Prevent Payment]** 1. Any of the payment means [a. Medical payment system or b. Computer system which performs an adjudication procedure and electronic payment or c. Computer system programmed to perform automated funds transfer.] including a computer system where claims fail to indicate approval of the action[utilization review]. or 2. A smart system for approving procedures. or 3. Computer system having the features of at least one identified structure within [CCL-Proposed Treatment], and at least one identified structure within [CCL-Indicia], that prevents payment until and unless the claim includes data indicating the action [utilization review] resulted in approval or authorization.
- **[CCL- Indicia-Treatments Ancillary Service]** Indicia of treatments provided by pharmacist, dentist, optometrist, audiologist, laboratories, medical specialists and others either using a printer or monitor screen.
- **[CCL-Provide Ancillary Service]** 1. An automated system, medical director or other suitable person indicates that payment will be made for a particular ancillary service

as an approved treatment protocol or part of an approved treatment protocol. 2. A provider electronically communicates a request for an ancillary service (such as a referral to a medical specialist) using the computer system. 3. Smart system for approving ancillary service treatments.

- **[CCL-DB Medical History]** Data base of Medical History [Predetermined items of medical history are any specific items which a database is established to collect where the items are items relating to patient data and heath history, items such as those found on patient medical charts and historical records, items that would be found on a patient summary report, items showing prior visits, treatments and tests, radiology and laboratory records and the like, caregiver comments and notes. May include items on a patient's chart and historical record. May also include a "medical chart summary report" and items typically displayed as part of "drug profiles"].
- **[CCL-DB Physical Profile]** Medical History includes physical profile[Attributes of the body, including things that would result from a physical examination of the patient such as the patient's height, weight, age, sex, and habits affecting the body (e.g., smoker, drinker)]
- **[CCL-Data Input Terminal]** A physician office terminal used to enter items of medical history.
- **[CCL-Responsive Data Input Terminal]** A physician office terminal that is responsive to inputs.
- **[CCL-Verify Authenticity]** Checking to make sure an individual who is a prospective patient has a genuine member identification number, which function can be accomplished 1. Manually through a computer terminal that is part of the system, or 2. Through the use of various types of data cards.
- **[CCL-Eligibility]** Verifying a member's authorization to participate in the system.
- **[CCL-Manual Keyboard**] Manual entry of information may be made by depressing keys on a keyboard.
- **[CCL-DB-Treatments-2nd-Opinion]** Database of that indicate **a**n opportunity or requirement to obtain a clinical evaluation by a provider other than the one originally making a recommendation for a proposed health care service to assess the medical necessity and/or appropriateness of the initial proposed health care service.
- **[CCL-Data Processor]** At least one computer processor, e.g., personal computer, mainframe, central processing system, microprocessor or the like.
- **[CCL-Data Bank Memory]** A repository of data; any substantial collection of data that can be stored and retrieved.
- **[CCL-Identify Preventive Health Routines]** Accessing recommendations for pertinent changes in lifestyle, such as changes in diet, elimination of smoking, reducing the consumption of alcohol, reducing weight, participation in an exercise program, reduction of blood pressure and the like.
- **[CCL-DB-Patient Data]** A database of unspecified patient data.
- **[CCL-DB-Terminal-Patient-Data]** An unspecified terminal to enter patient data.
- **[CCL-Payer DataPayer Data]** Data designating the identity of the payer: information indicating the insurance company, HMO, managed care organization, self-funded plan or other party who is responsible for paying for all incurred covered medical services and related benefits in accordance with the terms of a contract

between that entity and the patient (or a family member of the patient) and/or their employer.

- **[CCL-Data Representing Treatment]** Data representing treatment for each of a predetermined plurality of illnesses: Such data can be a name, code or abbreviation that stands for, denotes or symbolizes generally accepted treatments for any two or more illnesses. The Current Procedural Terminology (i.e., CPT) and International Code of Disease (ICD), Volume III codes are examples of widely accepted sets of such symbols. Data may be entered 1. A physician or a member of his or her staff enters the proposed treatment, such as through entering a CPT code, such provider wishes to propose in order to address each illness he or she has diagnosed the patient as having. or 2. A programmer or system administrator, in configuring and/or establishing the system, enters a list of treatments or treatment codes for any number of reasons relating to the operation and/or use of the system.
- **[CCL-DB-Personal Health Profile Data]** Information about a patient that is useful in evaluating a patient's health and including but not limited to information relating to the physical profile of a patient.

4.2.2 Asserted Claims with their Limitations

Claim 1: Claim Construction Limitations [CCL-Preamble], [CCL-Input Means], [CCL-Patient ID], [CCL-DB-Treatments-UR], [CCL-Payment Means], [CCL-Symptoms], [CCL-Proposed Treatments], [CCL-Indicia], and [CCL-Prevent Payment].

Claim 2: All of the limitation of Claim 1 and Claim Construction Limitations [CCL-INDICIA-Treatments Ancillary Service], and [CCL-Provide Ancillary Service].

Claim 4: Claim Construction Limitations [CCL-Preamble], [CCL-Input Means], [CCL-Patient ID], [CCL-DB-Treatments-UR], [CCL-Payment Means], [CCL-Symptoms], [CCL-Proposed Treatments], [CCL-Indicia], [CCL-Prevent Payment], and [CCL-DB Medical History].

Claim 5: All of the limitations of Claim 4 and [CCL-DB Physical Profile].

Claim 6: All of the limitations of Claim 4 and [CCL-Data Input Terminal].

Claim 7: All of the limitations of Claim 4 and [CCL-Responsive Data Input Terminal].

Claim 8: All of the limitations of Claim 7 and [CCL-Verify Authenticity].

Claim 9: All of the limitations of Claim 8 and [CCL-Eligibility].

Claim 12: All of the limitations of Claim 4 and [CCL-Manual Keyboard].

Claim 16: Claim Construction Limitations [CCL-Preamble], [CCL-Input Means], [CCL-Patient ID], [CCL-DB-Treatments-2nd-Opinion], [CCL-Payment Means], [CCL-Symptoms], [CCL-Proposed Treatments], [CCL-Indicia], and [CCL-Prevent Payment].

Claim 17: All of the limitations of Claim 16 and Claim Construction Limitations [CCL-INDICIA-Treatments Ancillary Service], [CCL-Provide Ancillary Service].

Claim 19: Claim Construction Limitations [CCL-Preamble], [CCL-Input Means], [CCL-Patient ID], [CCL-DB-Treatments-2nd-Opinions], [CCL-Payment Means], [CCL-Symptoms], [CCL-Proposed Treatments], [CCL-Indicia], [CCL-Prevent Payment], and [CCL-DB Medical History].

Claim 20: All of the limitations of Claim 19 and [CCL-DB Physical Profile].

Claim 21: All of the limitations of Claim 19 and [CCL-Data Input Terminal].

Claim 22: All of the limitations of Claim 19 and [CCL-Responsive Data Input Terminal].

Claim 23: All of the limitations of Claim 22 and [CCL-Verify Authenticity].

Claim 24: All of the limitations of Claim 23 and [CCL-Eligibility].

Claim 27: All of the limitations of Claim 19 and [CCL-Manual Keyboard].

Claim 34: Claim Construction Limitations [CCL-Preamble], [CCL-Input Means], [CCL-Patient ID], [CCL- INDICIA-Treatments Ancillary Service], [CCL-Provide Ancillary Service], [CCL-Symptoms], [CCL-Proposed Treatments], [CCL-Indicia], and [CCL-DB Medical History].

Claim 35: All of the limitations of Claim 34 and [CCL-DB Physical Profile].

Claim 36: All of the limitations of Claim 34 and [CCL-Data Input Terminal].

Claim 37: All of the limitations of Claim 34 and [CCL-Responsive Data Input Terminal].

Claim 38: All of the limitations of Claim 34 and [CCL-Verify Authenticity].

Claim 39: All of the limitations of Claim 34 and [CCL-Eligibility].

Claim 43: All of the limitations of Claim 37 and [CCL-Manual Keyboard].

Claim 52: Claim Construction Limitations [CCL-Preamble], [CCL-Input Means], [CCL-Data Processor], [CCL-Data Bank Memory], [CCL-Patient ID], [CCL- DB-Treatments-UR], [CCL-Payment Means], [CCL-Symptoms], [CCL-Proposed Treatments], [CCL-Indicia], and [CCL-Prevent Payment]

Claim 53: All of the limitations of Claim 52 and [CCL- INDICIA-Treatments Ancillary Service], and [CCL-Provide Ancillary Service]

Claim 54: All of the limitations of Claim 52 and [CCL-Identify Preventive Health Routines]

Claim 55: Claim Construction Limitations [CCL-Preamble], [CCL-Input Means], [CCL-Data Processor], [CCL-Data Bank Memory], [CCL-Patient ID], [CCL- DB-Treatments-UR], [CCL-Payment Means], [CCL-Symptoms], [CCL-Proposed Treatments], [CCL-Indicia], [CCL-Prevent Payment], and [CCL-Medical History].

Claim 56: All of the limitations of Claim 55 and [CCL-DB Physical Profile].

Claim 57: All of the limitations of Claim 55 and [CCL-Data Input Terminal].

Claim 58: All of the limitations of Claim 55 and [CCL-DB-Patient Data].

Claim 59: All of the limitations of Claim 58 and [CCL- Verify Authenticity].

Claim 60: All of the limitations of Claim 59 and [CCL-Eligibility].

Claim 63: All of the limitations of Claim 57 and [CCL-Manual Keyboard].

Claim 67: Claim Construction Limitations [CCL-Preamble]**,** [CCL-Terminal-Patient-Data], [CCL-Patient ID], [CCL-Payment Means], [CCL-Symptoms], [CCL-Proposed Treatments], [CCL-Indicia], [CCL-Prevent Payment], and [CCL-DB-2nd-Opinion].

Claim 68: All of the limitations of Claim 67 and [CCL- INDICIA-Treatments Ancillary Service], and [CCL-Provide Ancillary Service].

Claim 69: All of the limitations of Claim 67 and [CCL-Identify Preventive Health Routines].

Claim 70: Claim Construction Limitations [CCL-Preamble], [CCL-Input Means], [CCL-Data Processor], [CCL-Data Bank Memory], [CCL-Patient ID], [CCL-Payment Means], [CCL-Symptoms], [CCL-Proposed Treatments], [CCL-Indicia], [CCL-Prevent Payment], [CCL-DB-Medical History], and [CCL-DB-2nd-Opinion].

Claim 71: All of the limitations of Claim 70 and [CCL-DB Physical Profile]

Claim 72: All of the limitations of Claim 70 and [CCL-Data Input Terminal].

Claim 73: All of the limitations of Claim 70 and [CCL-Payer Data].

Claim 74: All of the limitations of Claim 73 and [CCL- Verify Authenticity].

Claim 75: All of the limitations of Claim 74 and [CCL-Eligibility].

Claim 78: All of the limitations of Claim 72 and [CCL-Manual Keyboard].

Claim 80: All of the limitations of Claim 70 and [CCL-Data Representing Treatment].

Claim 85: Claim Construction Limitations [CCL-Preamble], [CCL-Patient ID], [CCL-Proposed Treatments], [CCL-Indicia], [CCL-DB-Medical History], [CCL- INDICIA-Treatments Ancillary Service], and [CCL-Provide Ancillary Service].

Claim 86: All of the limitations of Claim 85 and [CCL-DB Physical Profile].

Claim 87: All of the limitations of Claim 85 and [CCL-Data Input Terminal].

Claim 88: All of the limitations of Claim 86 and [CCL- Verify Authenticity].

Claim 89: All of the limitations of Claim 88 and [CCL-Eligibility].

Claim 91: All of the limitations of Claim 85 and [CCL-Identify Preventive Health Routines].

Claim 93: All of the limitations of Claim 87 and [CCL-Manual Keyboard].

Claim 95: All of the limitations of Claim 85 and [CCL-Data Representing Treatment].

Claim 102: Claim Construction Limitations [CCL-Preamble], [CCL-Input Means], [CCL-Data Bank Memory], [CCL-Patient ID], [CCL-Payment Means], [CCL-Proposed Treatments], [CCL-Indicia], [CCL-DB-Medical History], [CCL- DB-Treatments-UR], [CCL-Symptoms], [CCL-Prevent Payment], [CCL-DB-2nd-Opinion], [CCL-DB-Personal Health Profile Data], and [CCL-Data Representing Treatment].

4.3 General References Summarizing Prior Art.

By 1990 Medical Informatics was a well-established field. In 1977 three societies covering overlapping aspects of the field merged into the American Medical Informatics Association (AMIA). AMIA sponsors annual meetings, titled *Annual Symposium on Computer Applications in Medical Care* (SCAMC). Those meetings often had keynotes promoting visions congruent with those of Cummings, but also hundreds of papers by researchers, physicians, and engineers trying to address the many details needed to bring, through use of computers and information systems, greater effectiveness to health care. Several thousand participants attended the meetings each year.

As Cummings surmised, much research in the area is sponsored by the National Institutes of Health (NIH), and its dissemination arm, The National Library of Medicine (NLM).

> "I felt there had to be, you know, other plug-and-play types of things.
> Q: what do you mean by plug-and-play?
> A: Where people – you have existing databases from, like the national institutes of health or someplace like that where you can take that module for treatment of a particular kind of disease and you can use it." [Cummings III:2000, p.314 l. 9-15]

Research relevant to financing and reimbursement of health care is also sponsored by other governmental agencies, as the Health Care Financing Agency (HICFA) and its successors -- cited by Cummings, the National Center for Health Services Research (NCHSR) and its successors as well as by a number of private foundations. The upshot is that it would have been very easy for an expert (as Mr.Singer) to gather an adequate collection of prior art in 1990, if that had been the goal.

4.3.1 The Next Three Generations of Healthcare Information Systems

4.3.1.1 Overview

[Halverson:1984] describes three generations of Healthcare Information Systems (HIS). His article presages the vision expressed in the specification section of the `105 patent.

The first generation combines an enhanced financial, reimbursement, marketing, and departmental budgeting system. This generation included standard insurance, patient billing algorithms, and data processing functions. In addition, this generation analyze with accuracy the costs of providing patient care by diagnosis within departments for both inpatient and outpatient activities, taking into account disease progression and severity, as well as the DRG classification (see Definition 3.4).

The second generation, built upon the first, is an extension to the current patient care and medical record database. This generation included the capture of patient care events, test results, and historical data on the interaction between physician-nurse-patient trilogy. This generation had communication between the financial and medical databases. Information captured included patient medication, reactions, patient diet, changes in diet, laboratory results, vital signs, surgical procedures, and disease severity, diagnosis, and medical treatment history of the patient. We are still trying to achieve this vision today. This generation was "from patient womb to tomb" and represented the Integrated Hospital Information System. The prospective payment systems has the ability to track not only the budgetary performance of departments and the costs by diagnosis of individual patient, but will analyze health care protocols to determine standards and norms by diagnosis. This generation could negotiate accurate reimbursement levels by diagnosis and disease progression.

The third generation of health information system will necessarily build on the first two-the integration of financial and patient management systems. This generation includes clinical decision support systems or medical expert systems, computer aids to diagnosis and for medical treatment, and treatment protocols. This generation is built on the technology of artificial intelligence system.

The authors are Mr. Halverson who is a managing partner of the Atlanta consulting firm of Management Associates. Mr. Halverson is a former employee of IBM; Pete, Marwick, Mitchel & Co.; and Technicon Data Systems. Steven A. Huesing (Steve) has been involved in Healthcare Information systems for over twenty years.

We now compare the asserted limitations with the **Three Generations HIS** vision. If one accepts the Allcare claims construction of the limitations where the preamble is not a limitation (i.e., the system need not be comprehensive), the system does not have to be completely automated, and that many of the `smart system` functions are performed manually with human intervention, then I can express the following opinions.

4.3.1.2 Invalidity and Anticipation of asserted claims

I hold the opinions that
the **Three Generations HIS** includes the limitation of **[CCL-Input Means]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-Patient ID]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-DB-Treatments-UR]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-Payment Means]** sense 3 by construction.

the **Three Generations HIS** includes the limitation of **[CCL-Symptoms]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-Proposed Treatments]** sense 3 by construction.

the **Three Generations HIS** includes the limitation of **[CCL-Indicia]** sense 2 by construction.

it is obvious that **Three Generations HIS** could be extended to include **[CCL-Prevent Payment]** sense 1 by one of ordinary skill in the art by simple technology extensions.

the **Three Generations HIS** includes the limitation of **[CCL-Provide Ancillary Service]** sense 2 by construction.

the **Three Generations HIS** includes the limitation of **[CCL- Indicia-Treatments Ancillary Service]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-DB Medical History]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-DB Physical Profile]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-Data Input Terminal]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-Responsive Data Input Terminal]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-Verify Authenticity]** sense 1 by construction.

the **Three Generations HIS** includes the limitation of **[CCL-Eligibility]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-Manual Keyboard**] by construction.

it is obvious that **Three Generations HIS** could be extended to include **[CCL-DB-Treatments-2nd-Opinion]** by one of ordinary skill in the art by known technology extensions.

the **Three Generations HIS** includes the limitation of **[CCL-Data Processor]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-Data Bank Memory]** by construction.

it is obvious that **Three Generations HIS** could be extended to include **[CCL-Identify Preventive Health Routines]** by one of ordinary skill in the art by simple technology extensions.

the **Three Generations HIS** includes the limitation of **[CCL-DB-Patient Data]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-DB-Terminal-Patient-Data]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-Payer Data]** by construction.

the **Three Generations HIS** includes the limitation of **[CCL-Data Representing Treatment]** sense 1 by construction.

the **Three Generations HIS** includes the limitation of **[CCL-DB-Personal Health Profile Data]** by construction.

Recall that we are assuming that the Allcare claims construction of the limitations where the preamble is not a limitation (i.e., the system need not be comprehensive), the system does not have to be completely automated, and that many of the `smart system` functions are performed manually with human intervention, then I can expresss the following opinion:.

It is my opinion that the asserted claims [1, 2, 4, 5, 6, 7, 8, 9, 12, 16, 17, 19, 20, 21, 22, 23, 24, 27, 34, 35, 36, 37, 38, 39, 43, 52, 53, 54, 55, 56, 57, 58, 59, 60, 63, 67, 68, 69, 70,

71, 72, 73, 74, 75, 78, 80, 85, 86, 87, 88, 89, 91, 93, 95, 102] of the `105 patent are invalidated by the **Three Generations HIS** because the limitations are either included or obvious by one of ordinary skill in the art, if one uses the Allcare claims construction.

It is my opinion that the asserted claims of the `105 patent are anticipated by the **Three Generations HIS** if one uses the Allcare claims construction because all asserted claims are invalidated.

4.3.2 AAMRS

4.3.2.1 Overview

In a 1975 Analysis of Automated Ambulatory Medical Record Systems (AAMRS) is presented covering existing systems at many health care organizations that were serving outpatients [Wiederhold:1975]. A guide was created and then used to interview 17 health care institutions in detail. The results are summarized in the report. The study presaged the features expected in future healthcare systems, with an emphasis on outpatient requirements, but included the desured linkages to inpatient information.

The study includes an Interview Guide for technical and operational evaluation of health care institutes concentrated on the ambulatory automated record systems, which lists the function that might exist in such systems. Areas covered (with respect to the `105 patent) on the topic of computer systems and hardware included:

keyboard, terminals, data entry, data storage, and the integration of functions.

Financial areas included:

billing, financial history of patient, monthly billing statement, third party bills (reimbursement claims), insurance carriers, financial management (billing, reimbursement claims processing, and cost analysis), ability to pay (bank name, credit check, and employer), budget management (fiscal decision makers), financial classification, and allocation of costs.

Ancillary services were discussed. Areas to be investigated regarding medical patient chart included:

identification of patient, complete patient record, flow sheet for the patient, worksheet for the patient, patient diagnosis, symptoms, patient medical history, physical exam info including height, weight, and sex, treatment and physician progress notes.

In the areas of wellness topics included:

health risk factors such as smoking, alcohol, accidents, and nutritional diet.

Scheduling of procedures is covered as well as follow-up services, triage, and referrals.

Patient benefit analysis indicated :

more time per patient, patient cost savings (reduced charge per service, reduced deductible, reduced subscription rates, fewer diagnostic tests and ancillary services, reduced waiting time, elimination of unnecessary visits due to referral process)

while management benefits centered around automation. The report described systems that were a combination of diagnosis, symptoms, treatment, and financial. Both quality of care reviews and utilization reviews were covered. No actual system investigated fulfilled all the expectations that the AAMRS report documented. However. that report expressed a vision that is congruent with the vision expressed in the `105 patent.

We note that even in 1975 the concept of a totally integrated and comprehensive health care management system was well established. Creating actual systems based on that vision is an ongoing process. The report also generated several papers and formed the basis for chapters in books, for instance [Blum:1986]. The report also provided input to [Wiederhold:1981] where examples of 4 health care computing systems are given, covering the breadth of information applications in health care: CCPDS (Public Health, Seattle), ECOG and RTOG (Cancer Trials, Harvard Medical School), TOD and ARAMIS (disease management, Stanford), COSTAR and HCHS (an HMO, the Harvard Community Health Plan), and POMCS (a hospital system, supported by IBM, in Coral Gables, Florida).

We will now compare the asserted limitations with an expected **AAMRS** . If one assumes the Allcare claims construction of the limitations where the preamble is not a limitation (i.e., the system need not be comprehensive), the system does not have to be completely automated, and that many of the `smart system` functions are performed manually with human intervention, then I can express the following opinions.

4.3.2.2 Invalidity and Anticipation of asserted claims

It is my opinion that
an **AAMRS** includes the limitations of **[CCL-Input Means]** by construction.

an AAMR includes the limitations of **[CCL-Patient ID]** by construction.

an **AAMRS** includes the limitations of **[CCL-DB-Treatments-UR]** by construction.

an **AAMRS** includes the limitations of **[CCL-Payment Means]** sense 3 by construction.

an **AAMRS** includes the limitations of **[CCL-Symptoms]** by construction.

an **AAMRS** includes the limitations of **[CCL-Proposed Treatments]** sense 3 by construction.

an **AAMRS** includes the limitations of **[CCL-Indicia]** sense 2 by construction.

it is obvious that **Three Generations HIS** could be extended to include **[CCL-Prevent Payment]** sense 1 by one of ordinary skill in the art by simple technology extensions.

an **AAMRS** includes the limitations of **[CCL-Provide Ancillary Service]** sense 2 by construction.

an **AAMRS** includes the limitations of **[CCL- Indicia-Treatments Ancillary Service]** by construction.

an **AAMRS** includes the limitations of **[CCL-DB Medical History]** by construction.

an **AAMRS** includes the limitations of **[CCL-DB Physical Profile]** by construction.

an **AAMRS** includes the limitations of **[CCL-Data Input Terminal]** by construction.

an **AAMRS** includes the limitations of **[CCL-Responsive Data Input Terminal]** by construction.

an **AAMRS** includes the limitations of **[CCL-Verify Authenticity]** sense 1 by construction.

an **AAMRS** includes the limitations of **[CCL-Eligibility]** by construction.

an **AAMRS** includes the limitation of **[CCL-Manual Keyboard**] by construction.

it is obvious that **AAMRS** could be extended to include **[CCL-DB-Treatments-Second Opinion]** by one of ordinary skill in the art by known technology extensions.

an **AAMRS** includes the limitations of **[CCL-Data Processor]** by construction.

an **AAMRS** includes the limitations of **[CCL-Data Bank Memory]** by construction.

an **AAMRS** includes the limitations of **[CCL-Identify Preventive Health Routines]** by construction.

an **AAMRS** includes the limitations of **[CCL-DB-Patient Data]** by construction.

an **AAMRS** includes the limitations of **[CCL-DB-Terminal-Patient-Data]** by construction.

an **AAMRS** includes the limitations of **[CCL-Payer Data]** by construction.

an **AAMRS** includes the limitations of **[CCL-Data Representing Treatment]** sense 1 by construction.

an **AAMRS** system includes the limitations of **[CCL-DB-Personal Health Profile Data]** by construction.

Recall that we are assuming that the Allcare claims construction of the limitations where the preamble is not a limitation (i.e., the system need not be comprehensive), the system does not have to be completely automated, and that many of the `smart system` functions

are performed manually with human intervention, then the following opinions can be expressed.

I hold the opinion that the asserted claims [1, 2, 4, 5, 6, 7, 8, 9, 12, 16, 17, 19, 20, 21, 22, 23, 24, 27, 34, 35, 36, 37, 38, 39, 43, 52, 53, 54, 55, 56, 57, 58, 59, 60, 63, 67, 68, 69, 70, 71, 72, 73, 74, 75, 78, 80, 85, 86, 87, 88, 89, 91, 93, 95, 102] of the `105 patent are invalidated by a system as presaged as an **AAMRS** because the limitations are either included or obvious by one of ordinary skill in the art, if one uses the Allcare claims construction.

I hold the opinion that the asserted claims of the `105 patent are anticipated by asystem as presaged as an **AAMRS** if one uses the Allcare claims construction because all asserted claims are invalidated.

4.3.3 Automated Hospital Information Systems

4.3.3.1 Overview

A study sponsored by The National Center for Health Services Research of the US. Dept of HHS and largely performed at the Center for Health Services research of The University of Southern California, under the leadership of Dr. Dorcas Hardy generated a 1981 workbook and guide for hospital administrators [Brian:1981]. The workbook covered suppliers of automated hospital information systems as well as a survey of several information systems at various hospitals. The workbook describes a list of more than 175 healthcare information applications.

In the AHIS work book you will find several charts. One chart, System Supplier vs. Applications, pages B-1 to B-11, contains a table of about two dozen suppliers of health care systems and which applications of the over 175 applications they provide. Another chart, Hospital vs. Applications, pages B-14 to B-21, contains a table of 29 hospitals and the applications actually installed, based on the same list of over 175 applications.

> The matrices are intended to serve as points of reference for hospital decision-makers to use in the process of developing system specifications and selecting an AHIS. The Hospital/Applications Matrix may be used to identify what types of applications are being employed by various sizes of hospitals. The System Supplier/Application matrix may be used to match against your hospital's desired application profile to determine the likelihood that the configuration desired will be available from one or more potential suppliers [AHIS:1981, p. B2].
>
> Technical elements of the descriptions include a listing of the applications offered and their mode of operation, the type of user interface equipment used, data retention characteristics and development support requirements. These elements are designed to be employed by personnel with the technical experience and

> expertise to determine the relevance of these characteristics to the individual hospital's desires and requirements [AHIS:1981, p. C1].

That various combinations of these features will be available in actual systems is made clear in the literature.

By 1981 not only was the concept of a totally integrated and comprehensive health care management system well established, the hospitals were moving towards a complete operational system. Which of the more than 175 candidate applications were present at a particular hospital was governed by available resources, urgency of need, and system dependencies, filtered through cost-effectiveness analyses and not by any great intellectual insight.

Section A of the manual describes 180 individual functions that a commercially available AHIS may perform. These functions are divided into 31 areas.

1. **Administrative Services**: Application functions includes: Budget Preparation – Other, Equipment Budget Preparation, Hospital Manuals and Procedures, Laundry Management, Message Communication, Salary Budget Control, Salary Budget Preparation, Space Use Planning and Control, Supplies Budget Preparation, System Security and Access Control, Telephone Lists for Patients, and Word Processing.
2. **Admission**: Application functions includes: Admission/Discharge/Transfer Notification, Address graph Plate Generation by Patient, Bed Assignment and Status, Label Generation by Patient, Newborn Registration with Mother's Data, Patient Date Base Historical Record Updating/Retrieval, Patient Identification Number Assignment, Patient Name Retrieval, Patient Number Retrieval, and Registration Reports and Form Printing.
3. **Cardiology**: Application functions includes: CCU Arrhythmia Monitoring System, EKG Historical Baseline by Patient, and EKG Interpretation.
4. **Data Processing**: Application functions includes: Central Hardware Utilization Measurement, Communications Utilization Measurement, Data Processing Cost Reporting, Data Volume Library Management, Diskette Utilization Measurement, Keypunch Production Reporting, Magnetic Tape Utilization Measurement, Project Control, Project Time and Effort Reporting, Remote Hardware Utilization Measurement, and Software Efficiency Measurement.
5. **Dietary**: Application functions includes: Dietary Master List, Menu Forecasting, Patient Menus, and Special Diet List.
6. **Emergency**: Application functions includes: Emergency Registration/Data Base Linkage, Emergency Room Statistics, Emergency Service Rosters, Patient Allergy/Drug Incompatibility, Risk Patient Tracking, and Trauma Registry.
7. **Energy/Environmental Management**: Application functions includes: Automated Elevator/Cart/Conveyor Control, Energy Use Controls, Physical Access Controls, and Temperature Controls.
8. **Epidemiology**: Application functions includes: Antibiotic Use Reporting, Detection of Bacterial Infection, Infection Notices, and Laboratory Culture Screening.

9. **Financial Management**: Application functions includes: Accounts Payable, Bad Debt Accounting, Budget/Actual Expense Reports, Capital Equipment Accounting, Capital Equipment Depreciation, Cash Accounts, Coordination of Insurance Benefits, Cost Allocation by Cost Center, Credit and Collections, Demand Billing, Financial Analysis of Occupancy and Revenue by Department, General Ledger Interface, Inpatient Accounting, Inpatient Billing, Insurance Billing, Medicare Billing, Outpatient Accounting, Outpatient Billing, Professional Billing, and Professional Fee: Revenue and Cash Reporting.
10. **Housekeeping**: Application functions includes: Housekeeping Schedule Reminders, Housekeeping Staff Scheduling, and Retrieve/Update Housekeeping Bed Records.
11. **Intensive Care**: Application functions includes: Intensive Care Patient Monitoring.
12. **Internal Medicine**: Application functions includes: Patient Medication Profile Retrieve/Update, Patient Plan of Care/Length of Stay, and Update Problem/Diagnosis for Patient.
13. **Laboratory**: Application functions includes: Analog Signal Acquisition, Blood Bank Management, Blood Donor File Management, Cadaver Organ and Tissue Retrieval, Clinical Lab Result Quality Control, Clinical Lab Specimen Control (log), Clinical Lab Workload Reporting, Digital Work Station Input, Histopathology Reporting, Laboratory Compacted Cumulative Historical Report by Patient, Laboratory Current Cumulative Report by Patient, Laboratory Historical Results Baseline by Patient or Characteristics of a Group, Laboratory Utilization Statistics, Other Work Schedules, Pathology/Cytology Comparative Result File Retrieval, Pathology/Cytology Reporting, Results Reporting, Schedule Clinical Lab Tests, Specimen Pick-Up Schedule, and Worksheets.
14. **Materials Management**: Application functions includes: Drug Distribution Monitoring, Non-Sterile Supplies Inventory, Office Supplies Inventory, Pharmacy Central Inventory, Purchasing Storeroom Inventory, and Sterile Supplies Inventory.
15. **Mechanical/Electronic Maintenance**: Application functions includes: Equipment Maintenance Schedules and Maintenance Staff Schedules.
16. **Medical Records**: Application functions includes: Discharge Abstract Preparation, Discharge Analysis and Reports, Discharge Summary Control, Disease Index Preparation, Medical Chart Reports, Medical Record Management, Medical Record Number Assignment, Operations Index Preparation, Patient Data Base Management, Patient Medical History Data Collection, Patient Record Data Collection, and Update Patient Data Base.
17. **Medical Staff**: Application functions includes: Access to Medical Research and Bibliography Searches, Medical Staff Activities Reporting, Medical Staff Privileges, Medical Staff Rosters, Patient Diagnosis/Order Profile Retrieve/Update, Physician BNDD Numbers (pharmacy), Physicians' Index, Physician Meeting Schedule Management, Physician/Inpatients Linkage for Reporting, Physician/Outpatients Linkage for Reporting and Scheduling, Private Clinic & Group Practice Included in Hospital Data Base, and Telephone Lists for Physicians.
18. **Nursing**: Application functions includes: Assign/Update Nursing Care Plan, Charge Compilation, Inpatient Census and Census Reporting, Nurses' Notes and Vital Signs Update Chart, Nurse Staffing Management, Nursing Schedule Automatic Reminders,

Nursing Staff Rosters, Order Format Tailoring to Type of Order, Order Transmission, and Pharmacy Floor Stocks Inventory.

19. **OB/GYN**: Application functions includes: Perinatal Risk Assessment.
20. **Oncology**: Application functions includes: Radiation Therapy Management and Tumor Registry.
21. **Outpatients**: Application functions includes: Ambulatory Therapy Scheduling, Outpatient Assignment and Status, Outpatient Scheduling, and Outpatient Visit Recording.
22. **Personnel/Payroll**: Application functions includes: Checks and Registers, Hours and Wage Reports, Interactive Training, Labor Cost Distribution, Labor Time Collection, Personnel History, Personnel Surveys and Questionnaires, and Wage and Salary Studies.
23. **Pharmacy**: Application functions includes: Cumulative Inpatient Drug Profile, Drug/Drug Incompatibility, Drug/Lab Incompatibility, Formulary (Pharmacy), Generic Name Cross Reference (Pharmacy), Narcotic Usage/Control, Patient Medication History, Pharmacy Manufacturing Reports, Prescription Issue/Label (Pharmacy), and Solutions (Pharmacy).
24. **Poison Control**: Application functions includes: Computerized Poison Identification and Poison Control and Antidotes.
25. **Psychiatry**: Application functions includes: Automated MMPI Interpretation.
26. **Radiology**: Application functions includes: X-Ray Jacket Control.
27. **Respiratory Therapy**: Application functions includes: Pulmonary Function Studies.
28. **Social Work**: Application functions includes: Discharge Care Plan.
29. **Surgery**: Application functions includes: Anesthesiology Monitoring, Operating Room/Recovery Room Log, Operating Room/Recovery Room Management, and Surgery Scheduling.
30. **Utilization Review**: Application functions includes: Utilization Review.
31. **Volunteers**: Application functions includes: Volunteer Services.

4.3.3.2 Invalidity and Anticipation of asserted claims

I hold the opinion that a system compliant with
an **AHIS** includes the limitations of **[CCL-Input Means]** by construction.

an **AHIS** includes the limitations of **[CCL-Patient ID]** by construction.

an **AHIS** includes the limitations of **[CCL-DB-Treatments-UR]** by construction.

an **AHIS** includes the limitations of **[CCL-Payment Means]** sense 3 by construction.

an **AHIS** includes the limitations of **[CCL-Symptoms]** by construction.

an **AHIS** includes the limitations of **[CCL-Proposed Treatments]** sense 3 by construction.

an **AHIS** includes the limitations of **[CCL-Indicia]** sense 2 by construction.

it is obvious that **AHIS** could be extended to include **[CCL-Prevent Payment]** sense 1 by one of ordinary skill in the art by simple technology extensions.

an **AHIS** includes the limitations of **[CCL-Provide Ancillary Service]** sense 2 by construction.

an **AHIS** includes the limitations of **[CCL- Indicia-Treatments Ancillary Service]** by construction.

an **AHIS** includes the limitations of **[CCL-DB Medical History]** by construction.

an **AHIS** includes the limitations of **[CCL-DB Physical Profile]** by construction.

an **AHIS** includes the limitations of **[CCL-Data Input Terminal]** by construction.

an **AHIS** includes the limitations of **[CCL-Responsive Data Input Terminal]** by construction.

an **AHIS** includes the limitations of **[CCL-Verify Authenticity]** sense 1 by construction.

an **AHIS** includes the limitations of **[CCL-Eligibility]** by construction.

an **AHIS** includes the limitation of **[CCL-Manual Keyboard**] by construction.

it is obvious an **AHIS** could be extended to include **[CCL-DB-Treatments-Second-Opinion]** by one of ordinary skill in the art by known technology extensions.

an **AHIS** includes the limitations of **[CCL-Data Processor]** by construction.

an **AHIS** includes the limitations of **[CCL-Data Bank Memory]** by construction.

an **AHIS** includes the limitations of **[CCL-Identify Preventive Health Routines]** by construction.

an **AHIS** includes the limitations of **[CCL-DB-Patient Data]** by construction.

an **AHIS** includes the limitations of **[CCL-DB-Terminal-Patient-Data]** by construction.

an **AHIS** includes the limitations of **[CCL-Payer Data]** by construction.

an **AHIS** includes the limitations of **[CCL-Data Representing Treatment]** sense 1 by construction.

an **AHIS** includes the limitations of **[CCL-DB-Personal Health Profile Data]** by construction.

Recall that we are assuming that the Allcare claims construction of the limitations where the preamble is not a limitation (i.e., the system need not be comprehensive), the system does not have to be completely automated, and that many of the `smart system` functions are performed manually with human intervention, then the following opinions can be expressed.

I hold the opinion that the asserted claims [1, 2, 4, 5, 6, 7, 8, 9, 12, 16, 17, 19, 20, 21, 22, 23, 24, 27, 34, 35, 36, 37, 38, 39, 43, 52, 53, 54, 55, 56, 57, 58, 59, 60, 63, 67, 68, 69, 70, 71, 72, 73, 74, 75, 78, 80, 85, 86, 87, 88, 89, 91, 93, 95, 102] of the `105 patent are invalidated by an **AHIS** compliant system because the limitations are either included or obvious by one of ordinary skill in the art, if one uses the Allcare claims construction.

I hold the opinion that the asserted claims of the `105 patent are anticipated by an **AHIS** compliant system if one uses the Allcare claims construction because all asserted claims are invalidated.

4.3.4 Hospital Information Systems 1985

[HIS:1985] is a 1985 published book on the state of the art of hospital information systems. This book covers the application topics of financial, nursing, information systems, laboratory systems, pharmacy systems, and medical records as they apply to community hospitals. Information about many hospitals and suppliers of applications was provided.

4.3.5 Hospital Information Systems 1988

[Wiederhold:1988] is a 1988 encyclopedic review of Hospital Information Systems (HIS) technology. The HIS as described in the paper consists of over 150 functions with the sharing of information between both administrative and clinical systems while using integrated data, knowledge, and information in a synergistic approach. The HIS as described in the paper may use terminals, teletypes, telephones, machine-readable forms, shared large-scale computers, light pens, video display terminals (VDTs), bar codes, databases, and distributed systems. The HIS describes a robust clinical medical record supporting diagnosis, treatment, prognosis, nursing care plans, clinical decisions, order entry, and other ancillary services. Many financial sources including individuals, health insurance, Medicare and Medicaid, military, grants, investments, local government, and philanthropic. In the article are examples of utilization review, including financial, treatment, length of stay (LOS), treatment options reflecting different prognosis, medical audit, and inventory. Medical record concepts are described.

4.4 Health Care Support Systems that Provide Prior Art

In this section we briefly review reports and description of Computer-based Health Care Data processing Systems or Health-care Management Systems. The systems we list are practical composed systems. There have been many systems that preceded the `105 patent application which performed the tasks, often in concert with other systems and some manual operation, similar to the Trigon system that the owners and experts representing the '105 patent assert to be infringing on their patent.. We have shown in Sections 1 and 2, that such infringement claims represent an unwarranted broadening of the patent. Any such broadening raises the issue of prior art that was not brought forward by the applicants, as described in the Section 4.1 above. Neither was a search for such prior systems performed by the patent examiner. We do not know enough about the operation of the patent office in those days to guess why prior systems with similar functionality were overlooked. In the view of the Allcare's expert who carried out the prior art search the `105 patent specified full automation within a single automated system.

Since the `105 patent claims to be comprehensive we can only include a small sample. We restrict ourselves to systems involving computer-based automation. Were we to accept the claims that the `105 patent covers fully manual data-processing as well, then there is no way that comprehensiveness can be achieved. We'd have to go back to the [Flexner:1910] report, which provided the basis for medical record keeping as it is practiced today in the United States. See also [Shortliffe:1990, pp. 185-187] for a brief historical summary.

We note that comparisons of extant systems, with

- problems due to complex institutional settings,
- difficult financing,
- imperfect hardware,
- lack of trained people, and
- flaky technology.

with a vision where

- the institution is supportive and all-encompassing,
- money is not a constraint,
- hardware is perfect,
- smart, certified people with deep medical and computing insights are available, and reliable technology is available that can even perform tasks that are beyond the state of the art

are bound to prefer the vision. Note, for instance, that even the Veterans Administration system of the Defense Department could not obtain sufficient resources to implement their plans.

4.4.1 Help

The HELP system had its origins in the LDS Hospital Cardiovascular Laboratory in 1954 [Gardner:2000], under the leadership of Dr. Homer Warner. The program took in clinical findings, laboratory results, symptoms, and conditional probabilities as input and produced a list of probable diseases that could account for the clinical findings. In addition, the system could generate a more complete differential diagnosis. It operates in the context of a larger health care system, and derivatives were commercially marketed by Control Data Corporation.

4.4.2 Massachusetts General Hospital

Massachusetts General Hospital (MGH) has been one of the primary sites for health care innovation, including collection of structured medical records, use of records for health care analysis, support for HMO services, as the **COSTAR** system, and development of infrastructure software such as **MUMPS** [Wiederhold:1981], the MGH Utility Multi-Programming System. The prime site was the **Harvard Community Health Plan**, and outpatient focused HMO, with a variety of linkages to the hospitals that were used when the health plan members required inpatient services. The aggregate of the systems forms a comprehensive system, although not as tightly integrated as Cummings' vision demands.

Its energetic director, Octo Barnett, has advocated the development of effective health care information systems in an incremental and modular fashion, to avoid the failures associated with attempts to build large, comprehensive health care systems. The modular approach implements first the services that bring the greatest immediate benefits, and then develops further services on top of that infrastructure [Barnett:1967]. The wisdom of that approach has been borne out in practice. There are many health care systems in operation that provide benefits to their owners, they are mostly composed of modules, as the Trigon systems, and there are no successful systems that were designed to be comprehensive, as envisioned in the `105 patent.

4.4.3 Brigham and Woman's Hospital in Boston

Brigham and Woman's Hospital in Boston installed systems for inpatient care using support from Meditech (see Section 4.6.1) , adapting the outpatient-oriented systems developed at the Harvard Health Plan. Development was gradual and is continuing, as outlined by the [Bleich:2000] report. Other hospitals, as **Beth-Israel**, also in Boston eventually joined the effort. The Meditech systems have been interfaced with a variety of functions, so that both hospital routine operations and the substantial research interest of its faculty and students are supported. Many papers describe aspects of the innovations at these hospitals. [www.brighamandwomens.org]

4.4.4 The Veteran's Administration

The Veteran's Administration (VA) is a long time user of automation for both its inpatient and outpatient facilities. The VA provides comprehensive services to veterans and their families. Wellness, as control of alcoholism etc., is a concern to the VA, since

many veterans suffer from the effects of stress induced by their experiences, greatly increasing the cost of veterans' healthcare. Its health information system, the Decentralized Hospital Computer Program (DHCP) was initiated in 1982, and had its core program in operation, including outpatient and inpatient modules by 1987. It relies greatly on effective electronic communication, since veterans are eligible to visit any of the many VA facilities., and do so. A total of 51 service modules were envisaged and planned for. At the core of its system is a Comprehensive Medical record, congruent with the vision presented by Cummings in the `105 patent. Its billing structure is specific to the Defense Department, but validation of eligibility is an important and complex aspect and a full accounting of services supplied to its patients is maintained. A module for billing of ineligible fees was in development in 1987. The software used is again MUMPS-based, supported by several vendors.[VA:1990], Being a government operation, its functions are very well documented and in the public domain. The cost of developing and operating such a comprehensive system were worrisome to the government, and a 1987 GAO study recommend a slowing down of the development of additional modules [GOA:87]. Note that the problem was not one of lack of vision, concepts, or technological and medical understanding of the methods needed to build the system, but one of financing and marshalling enough management and technological resources within the Department of Defense.

4.4.5 TDS, formerly Technicon

TDS, formerly Technicon Medical Information System, is a hospital focused system that innovated the integrated flow from order entry at the bedside to billing. Its development was initiated by Lockheed Corporation, and installed starting September 1971 at El Camino Hospital in Mountain View, California. An evaluation of its effectiveness was sponsored by the National Center for Health Services Research [Batelle:1973] and widely disseminated.
The Clinical Center at NIH was served by a TDS installation when the `105 patent was conceived, and has had regular tours to show its inpatient and outpatient operations. Due to its research focus it does not do routine billing.

4.4.6 The Kaiser Permanente Health Plan

The Kaiser Permanente Health Plan is an HMO that has been a long-term innovator in automated processing. The vision of Dr. Morris Collen, the long-term leader of its information system, stressed support for wellness through its Health-testing and guidance programs, as well as inpatient and outpatient care support. Since the Kaiser operation is a medical partnership actual agreement has been hard to achieve so that different sites may offer automation for inpatient, or outpatient, or both services, or none. As a leader in the HMO field, its concept have been widely studied and analyzed

4.4.7 Promis

Promis, developed by Dr. Larry Weed the University of Vermont introduced the Problem-Oriented Medical Information System built in the early 1970s. Physicians at the

hospital used computer terminals to order tests and drugs, record medical history, physical exam data, and progress notes. Promis implemented Weeds vision of the problem-oriented medical record in which all diagnostic and therapeutic actions are tied to an underlying patient problem. Promis at summarized in [Shortliffe:1990], see also [Weed:1981] and [Weed:1985]. The technology was also adapted into nearby private outpatient clinics [BjornC:1970].

4.4.8 Regenstrief

The Regenstrief Clinic provides outpatient services within the Indiana University Medical Center. Dr. Clem McDonald and his colleagues introduced the RMRS (Regenstrief Medical Record System) in the 1974 time frame. By 1988, it maintained substantial medical histories for at least 250,000 patients with over 25 million separate patient observations. The Regenstrief Clinic and its computer system is part of a large academically-based health care system that also handles appointment scheduling and charge capture. Mathods developed for communicating data from extrernal clinical laboratories in the 1980's have become the accepted standard for health care institutions. The system includes support for quality-assurance, flow sheet summary, problem lists, prescriptions, order tests, physician progress notes, and encoding of information. Specialized subsystems provided services that carry out some of the functions indicated as being smart in Allcare reports: diabetes management, weight control, and the like, although none map symptoms to treatments. Numerous papers describing the system and analyzing cost-benefit tradeoffs of their health care system modules have appeared in the literature; the system is summarized in [Shortliffe:1990]

4.5 Health Care Reimbursement Systems

Reimbursement-oriented systems have not been as well described in the formal literature since they attract less formal attention. But, because of their importance to the survival of the health care system, they have actually received more support than patient care systems. We reserve the right to augment this section as information becomes accessible.

4.5.1 Bank One

Bank One N/A. a financial institution, designed and developed a Medical Payment System (MPS) and started marketing it in 1989. It was placed into operation in Wisconsin in 1992-1993. The system is described in a brochure and in the deposition of Gerald Kurtyka, Vice president at the bank in charge of MPS [Kurtyka:2000]. This system was divulged to Mr. Cummings [Kurtyka:2000, pp.6-7] at an AHA meeting in Phoenix, AZ, in May 1990.

> Mr. Cummings was very excited and stated "I've been working on exactly the same thing!".

Follow-up contacts included meetings with Cummings and Conner; and several visits were made to the Florida Hospital, where Mr. Cummings represented himself as an employee of Florida Hospital, acting in his capacity as an officer of Florida Hospital, i.e., as a potential customer of Bank One. [Kurtyka:2000, pp.7-13]. This system was not included in the prior art presented to the U.S patent office.

4.5.1.1 Overview

[BankOne:1989] was a proposed 1989 Medical Payment System. The system was an electronic, comprehensive, and integrated medical payment system for health care providers. Participants included providers, patients, employers for enrollment, and insurance companies, with the Bank providing a clearinghouse function, Features included adjudication, utilization, reimbursement claims processing, payment, data input terminal, swipe cards, and electronic transmitting funds. Medical information included diagnosis, procedures, treatments, using ICD and CPT codes. Drug codes were contemplated for pharmaceutical adjudication. Support for obtaining second opinion, making referrals, and utilization review was included. The system did not instruct the release of payment until there was confirmation that the review has been obtained. To some extent it also provided a vision, but during 1992-193 substantial parts had been implemented at a Wisconsin health care site [Kurtyka:2002].

We will now compare the asserted limitations with the proposed Bank One system. If one assumes the Allcare claims construction of the limitations where the preamble is not a limitation (i.e., the system need not be comprehensive), the system does not have to be completely automated, and that many of the `smart system` functions may be performed manually with human intervention, then I hold the following opinions.

4.5.1.2 Invalidity and Anticipation of asserted claims

It is my opinion that
the **Bank One** system includes the limitations of **[CCL-Input Means]** by the feature of data input terminal.

the **Bank One** system includes the limitations of **[CCL-Patient ID]** by the presence of a swipe card.

it that **Bank One** system was designed to allow inclusion of **[CCL-DB-Treatments-UR],** and enabled its implementation by a person of ordinary skill in the art by facilitate ICD, CPT, and utilization review.

the **Bank One** system includes the limitations of **[CCL-Payment Means]** sense 1 by construction.

the **Bank One** system includes the limitations of **[CCL-Symptoms**] by construction.

the **Bank One** system includes the limitations of **[CCL-Proposed Treatments]** sense 3 by construction.

the **Bank One** system includes the limitations of **[CCL-Indicia]** sense 2 by construction.

the **Bank One** system includes the limitations of **[CCL-Prevent Payment]** sense 1 by construction.

the **Bank One** system includes the limitations of **[CCL-Provide Ancillary Service]** sense 2 by example of a referral.

it is obvious that **Bank One** system could be extended to include limitation **[CCL-Indicia-Treatments Ancillary Service]** by one of ordinary skill in the art by example of referral.

it is obvious that **Bank One** system could be extended to include limitations **[CCL-DB Medical History]** by one of ordinary skill in the art by construction, ICD, and CPT.

it is obvious that **Bank One** system could be extended to include limitations **[CCL-DB Physical Profile]** by one of ordinary skill in the art by simple extension.

the **Bank One** system includes the limitations of **[CCL-Data Input Terminal]** by construction.

the **Bank One** system includes the limitations of **[CCL-Responsive Data Input Terminal]** by construction.

it is obvious that **Bank One** system could be extended to include limitations **[CCL-Verify Authenticity]** sense 2 by one of ordinary skill in the art by simple extension of known processes.

the **Bank One** system includes the limitations of **[CCL-Eligibility]** by construction.

it is obvious that **Bank One** system could be extended to include limitations **[CCL-Manual Keyboard**] by one of ordinary skill in the art by simple extension of known technology.

the **Bank One** system includes the limitations of **[CCL-DB-Treatments-Second-Opinion]** by construction.

the **Bank One** system includes the limitations of **[CCL-Data Processor]** by construction.

the **Bank One** system includes the limitations of **[CCL-Data Bank Memory]** by construction.

it is obvious that **Bank One** system could be extended to include limitations **[CCL-Identify Preventive Health Routines]** by one of ordinary skill in the art by simple extension of treatments.

it is obvious that **Bank One** system could be extended to include limitations **[CCL-DB-Patient Data]** by one of ordinary skill in the art by simple extension of technology.

it is obvious that **Bank One** system could be extended to include limitations **[CCL-DB-Terminal-Patient-Data]** by one of ordinary skill in the art by simple extension of technology.

the **Bank One** system includes the limitations of **[CCL-Payer Data]** by construction**.**

the **Bank One** system includes the limitations of **[CCL-Data Representing Treatment]** by CPT**.**

it is obvious that **Bank One** system could be extended to include limitations **[CCL-DB-Personal Health Profile Data]** by one of ordinary skill in the art by simple extension of technology.

Recall that we are assuming that the Allcare claims construction of the limitations where the preamble is not a limitation (i.e., the system need not be comprehensive), the system does not have to be completely automated, and that many of the `smart system` functions are performed manually with human intervention, then the following opinions can be expressed.

I hold the opinion that the asserted claims [1, 2, 4, 5, 6, 7, 8, 9, 12, 16, 17, 19, 20, 21, 22, 23, 24, 27, 34, 35, 36, 37, 38, 39, 43, 52, 53, 54, 55, 56, 57, 58, 59, 60, 63, 67, 68, 69, 70, 71, 72, 73, 74, 75, 78, 80, 85, 86, 87, 88, 89, 91, 93, 95, 102] of the `105 patent are invalidated by the **Bank One** system because the limitations are either included or obvious by one of ordinary skill in the art, if one uses the Allcare claims construction.

I hold the opinion that the asserted claims of the `105 patent are anticipated by the **Bank One** system if one uses the Allcare claims construction because all asserted claims are invalidated.

4.5.2 Blue Max

Blue Max ([Bluemax:1990], [Medicalis:1986], [Medicalis:1986a]) was a Medical office automation system built by Health Management Corporation in association with Blue Cross and Blue Shield of Virginia in the 1986 time frame. This was a practice management system: "a unified financial, clinical and office automation healthcare network".

Areas covered (with respect to the `105 patent) on the topic of computer systems and hardware included a micro-based computer system on the desktop. Financial areas included payment (debit or carrier), insurance forms, payment information, flexibility in billing, patient or account information, charge slips, bank deposit slips, practice's billing requirements, monitoring of year-to-date and lifetime benefits and deductible amounts for each type of insurance plan, payment adjustments, monthly financial reports, accounts receivable aging, and electronic reimbursement claims. Areas discussed about the medical patient chart included medical records, patient information (names, addresses, phone numbers), patient identification code, diagnosis, prescriptions, notes, treatment plans, rule-outs, test results, last visit date, clinic rounds report, and treatment plan. There was encoding of services and diagnosis, pre-authorization, and report generation. The system contained an On-line Electronic Index and Dictionary.

There is a list of procedures that require pre-authorization from the insurance company. Each patient may have a treatment plan. "System VI brings up an easy-pick list of pre-authorized procedures from the patient's treatment plan. Then, just select the item ... ". The system includes electronic claims submission and keeps track of referral sources from other doctors. Authentication of the provider is by password functionality.

There is a list of 300+ proposed future features. They include:

Item 16. Link Information from a self-administered patient history (SAPH) into an expert system database and print flow charts for diagnostic follow up (e.g. rule-outs, etc.).
Item 35. Employer codes.
Item 44. Print a group plan utilization report.
Item 109. Add a frequency of diagnosis by provider report.

Item 110. Add a patient visits by doctor report.
Item 121. Calculate patient visitation = number of patients over number of new patients.
Item 122. Calculate office visit average.
Item 123. Calculate case average.
Item 125. Allow pre-verification before actual billing, making sure all needed info is there.
Item 135. Add artificial intelligence "guardian agent" which are (monitoring) situations you define. If the system spots them, it will take appropriate action, e.g. warn you if a patient hasn't been in for over 6 months to verify the address, or any other situation.
Item 140. Have the system automatically calculate the EOB of payments.
Item 228. Have a documentation line (free-form, one line) that will appear whenever patient is accessed (for medical alerts, etc.).
Item 248. Build more "smarts" into the recall (data-merge) system to warn patients when certain permanent diagnosis are pulled. The system can generate special forms/reminders the patient should think of, including possible questions, things to bring, follow-ups, etc.
Item 336. Let charge slips include all activities, not just pre-auths.

4.5.3 LifeCard

[LifeCard:1985] is the brochure on the LifeCard system of Blue Cross/Blue Shield of Maryland dated 1985.

LifeCard is a card-base system the size of a credit card. The card is a laser/optical memory card that can hold up to 800 pages of patient information. It requires use of a PC with a read/write unit and special software at the provider office.

On the card, information is stored including health history, identification, an identification photo, diagnosis, treatment plan, hospital pre-admittance, insurance coverage information, the exact amount that will be covered, eligibility and medical coverage, lab work, blood type, current medications, prior cardiac episodes, seizures, discharge summary, images produced by EKGs, EEGs, X-rays, CATs, NMRs, operative procedures, results of diagnostic and therapeutic procedures, complete summary of all medicines prescribed, automatic reimbursement claim processing, pre-emergency information, follow up visits, drug allergies, security, authorization of usage, and confidential data security.

The card has supporting systems to assist in the coding of diagnoses and DRGs (see Definition 3.4). The card will help reduce the problem of polypharmacy (prescription of drugs by more than one physician).

The card will improve cost efficiency and the wellness of the subscriber.
This card is also named "Health Management System". There is support for obtaining second opinions.

A person obtaining a LifeCard will obtain a free health review when they get the card.

LifeCard is a trademark of Health Management Systems, Inc.

4.5.4 Opti-Med

Opti-Med [Andrusyshyn:2000] [Wellman:2000] or Optimed is a health care management system providing pre-certification and pre-authorization of requested treatment procedures and utilization review. It is a commercial successor to work that was performed at the Health Data institute in Newton, MA, starting around 1987. Opti-Med systems were sold to insurance carriers such as Blue Cross, Humana, and Chrysler for employee benefit support. The Opti-Med programs review the medical necessity, appropriateness of location (inpatient, outpatient, or physicians office), and appropriateness of length of stay of a given treatment regiment given diagnostic codes and other data. Opti-Med includes a complete set of clinical protocols. The system supports referrals and second opinions. The early system relied on telephonic communications between providers and the insurance companies that used it. The company was purchased by SHPS in 1997, and the software became a module of their health care support package.

From [Holland:2002D]

> A. It was a product owned by the Health Data Institute and in 1990 the Health Data Institute was broken up and sold by the parent company, Baxter, and myself and two friends bought the Optimed Medical Systems.
> Q. And you say it was a phone-based system?
> A. Yes. It was made for nurses that sat at a terminal and read questions off the screen and doctors would call in and they would talk to the doctor and their staff, answer questions and then would produce a decision to pre-authorize, assign a length of stay.
> Q. What was the typical response time for that type of thing to happen?
> A. Typical phone call?
> Q. Yes.
> A. It was five to 12 minutes.
> [Page 105 Lines 1-22, Page 106 Lines 1-2]

4.5.5 The Birmingham System

[Wirtschafter:1975] was a Blue Cross reimbursement system by phone developed at the University of Alabama in Birmingham, Alabama, servicing patients and physicians with remote outreach.
We are obtaining more information about this project.

4.5.6 Metropolitan Life Insurance Company

Proposal for a claims system for the Metropolitan Life Insurance Company by Noble Lowndes International Inc. in the 1985 time frame. [MetropolitanLife:1985]

This was a proposal to extend the existing Lowndes system for Metropolitan Life. The adjudication system was called Automated Claims Entry System (ACES). The integrated system included the features of claim history, patient identification, eligibility checking, pre-certification, benefits checking, per-cause limitations based on diagnosis, payment system, EOBs, on line claim entry, UB82 claim forms, authentication, and benefit verification. The system was for hospital and physician care with support for drug, medical, vision, and ancillary system. Information was encoded using ICD9, CPT4, and DRGs. The system uses IBM computers and databases. The system supported pre-certification and referrals. Utilization review was done for cost effectiveness and included hospital length of stay. Claims could be placed in "pend" status. The system supports a "fast pay" mode where claims were paid and then post-adjudicated and adjusted.

4.6 Subsystems for Healthcare Functions

As Kaliski insists, and Singer denies, Health Care information systems must be composed of many pieces of software and then interfaced to form a coherent whole. The healthcare enterprise is just too large and dynamic to allow one vendor or supplier to control it all. Cummings was aware of that:

> "Q: And after these rules are developed, the rules are not finished at that point, correct? A: No, That – basically, medicine is always dynamic" [Cummings :2000 III, p.323 l. 3-6]

Most single system health care systems are no longer in operation because they could not adapt adequately to the variety of changes imposed by changes in financing, medical practice, and demographics. New concepts are typically innovated in distinct projects, and, if effective, eventually interfaced and perhaps integrated into the larger, compose systems. We will list the instances in approximately chronological order, although many of them had long gestation times, and the point of conception may not be known.

The number of individual projects that comprise relevant prior art numbered in the hundreds at the time the patent was applied for. The patent cited some, focusing on the use of `smart card' technology. We only mention ones cited or implied - often misspelled - in the expert reports.

4.6.1 Meditech

Meditech commercialized the MGH developed MUMPS software technology in the middle 1960's. This technology allowed operations on modest computers, easy programming, and a data file structure that was oriented towards medical information. Meditech provided the infrastructure for many subsequent innovations. Among others it supported Beth Israel, Boston Brigham and Women's and related hospitals, as well as the Veterans Administration hospitals and other military care centers. See [Bleich:2000].

4.6.2 Internist

Internist [cited by Blevin] summarized in [Shortliffe:1990], is a large diagnostic program developed at the University of Pittsburgh School of Medicine in the early 1970's. It maps findings and disease manifestations into diseases. It tried to capture the depth of knowledge of Dr. Jack Mayers, one of the most renowned diagnosticians of our times. To each finding – sign or symptom - is assigned an evoking strength, a frequency weight, and an important number. Internist then used a scoring scheme to establish the differential diagnosis from a collection of such findings. Being based on the experience of a single expert, versus on committee deliberations, provides a great deal of consistency in quantifying the findings. In one 1982 study involving 19 different patients with 43 diagnoses, Internist correctly identified 25. Originally Internist ran on a mainframe computer, but in the early 1980s the program was adapted to run on a microcomputer as

QMR (Quick Medical Reference). Although development is continuing, it has not yet reached a competence to serve in primary medical settings.

4.6.3 DXplain

DXplain [cited by Blevin] is a diagnostic decision-support system developed at Massachusetts General Hospital and was developed by Octo Barnett and his staff during 1987 to 1990. One of the goals of DXplain is to generate a list of possible diagnoses from a group of clinical findings. Other information is available, such as the frequency that a symptom occurs in a particular disease, or the chance that a particular disease is present given a certain finding.

A disease profile consists of a set of clinical findings the developers have decided are relevant. For each finding listed for a disease, three attributes are stored: term frequency, term-evoking power, and term importance. Term frequency quantifies how often a finding occurs in a disease, term-evoking power states how strongly the finding supports the diagnosis of the disease, and term-importance measures how consequential is the finding. DXplain also stores the disease prevalence for each disease or the baseline likelihood of a disease in the general population, or how consequential the disease is.

DXplain generates a list of possible diagnoses using a pseudo-probabilistic algorithm. It first evaluates the term importance and term-evoking strength of each finding-diagnosis pair and then calculates a summary score for each disease. A disease score is most influenced by positive findings that have high term-evoking strength. Findings with intermediate evoking strengths and high term importance contribute moderately to the summary score. After DXplain evaluates each clinical finding, it displays the highest ranked diagnoses divided into "common diseases" and "rare or very rare diseases."

DXplain is currently used by many individuals and institutions around the world. Because of concerns that proper interpretation of its output requires medical knowledge, DXplain is available only to physicians.

4.6.4 Mycin

Mycin is the most cited rule-based system in Medicine. It is employed only when a diagnosis of Meningitis has been reached and provides advice on which of 5 alternate antibiotics to employ before clinical laboratory testing has determined which one tests to be the most effective. A rule-based approach is reasonable here because:
1. a diagnosis exists.
2. the number of alternatives treatments is small.
3. all the treatments have little risk, they only differ in effectiveness. The treatment advice is only valid for the few days needed to obtain the laboratory report.
4. the actual medication decision is made by the patient's physician. [Cummings II:2000, p. 186 l. 17-21].
Mycin was developed by Dr. Shortliffe at Stanford University during 1975-1980 [Shortliffe:1976].

4.6.5 Oncocin

Oncocin [cited by Blevin xxx] is a system for Clinical Oncology Data Management, intended to assist physicians in collecting appropriate data for making good decisions for ongoing treatment. All patients have already been diagnosed and treatments have been prescribed. It was developed by Shortliffe et al. during 1984-1986 in part due to the frustration of having inadequate data available from routine data for rule-based systems of the Mycin style (q.v.).

4.6.6 Acid-Base Disorders [Bleich:1969]

With the advent of electronic computers (in the 1969 time frame) that operate in the time-sharing mode, it has become possible to develop an automated system that can assist a physician in solving clinical problems. In the present study a Teletype terminal has been linked to a time-sharing computer which has been programmed to evaluate clinical and laboratory information concerning patients with acid-base disorders. The program checks the data for evidence of internal consistency and requests additional information as needed to solve the acid-base aspects of the clinical problem. If sufficient information is provided, the program generates an evaluation note designed to review with the physician the pathophysiology of the disorder and to assist him in its management. If the input data are incomplete, the program draws the most useful conclusions possible based on the data provided, specifies the limitations which pertain to these conclusions, suggests further studies designed to circumvent these limitations, and while awaiting the results, suggests appropriate interim therapeutic measures.

4.6.7 Ovid [Ovid:2002]

Ovid offers a rich, inter-linked knowledge environment designed to deliver authoritative answers to questions quickly and easily. Ovid search software supports full text journals and bibliographic. Support for over 800 journals. Support for medical, nursing, and pharmaceutical reference textbooks from multiple publishers. Intended for working physicians, nurses, and pharmacists, Ovid delivers evidence-based summary information on clinical topics as well as clinical decision support and education resources, and drug information.

4.7 Summary

Predating the `105 patent is significant prior art. I hold the opinion that the **Bank One** system, a system containing the features described for **AAMRS**, the **AHIS** workbook, and the **Three Generations HIS** system all anticipate the asserted claims of the `105 patent as construed by Allcare's claims construction chart when it is asserted that the preamble is not a limitation, the system does not have to be completely automated, and that many of the `smart system` functions are performed manually with human

intervention. The anticipating references are only examples. Further literature searches would greatly increase the number of anticipating references.

5. Reviews and Rebuttals of Plaintiff's reports and depositions

Index by Author.

- 5.10 Barber et al., patent 4858121 August, 1989.
- 5.1 Cummings: [2000] and [2002].
- 5.15 Deschenes et al., patent 3697693 October, 1972.
- 5.14 Doyle, Jr. et al. 4916611 April 1990.
- 5.6 Holland:2002 Report.
- 5.7 Holland's 2002 Deposition.
- 5.5 Kaliski:2002.
- 5.9 Krieger: Analysis of Prior Art by Paul Krieger.
- 5.8 Kurtyka, Expert Report.
- 5.16 Mohlenbrock et al. , patent 5018067 May, 1991.
- 5.12 Pritchard, patent 4491725 January, 1985.
- 5.17 Sinay, patent 4290114 September, 1981.
- 5.2 Singer:1990 Quality Assurance.
- 5.3 Singer:2000.
- 5.4 Singer: 2000 and 2002 Depositions.
- 5.13 Valentino, patent 4648037 March, 1987.
- 5.11 Watanabe, patent 4797543 January, 1989.

Since the submitted material is voluminous, we reserve the right to append further comments and analyses to this Section.

5.1 Cummings: [2000] and [2002]

In the initial depositions [Cummings:2000] and the later following deposition [Cummings:2002], there are items which are presented clearly, and items where Cummings is not able to be precise. Cummings presents high-level issues in health care clearly. He is enthusiastic about the need for comprehensive health care. Cummings becomes vague and inconsistent when specific health care or computer system detail is probed. His professional focus has obviously been on marketing improved health care systems, not building or managing them.

5.1.1 Vision

Cummings presents a system that he never, even in part, could implement, or that he even contemplated implementing. The disclosure ignores both the inability of current technology as well as organizational issues, namely that no single organization in the United States could be authorized to integrate all the required functions.

> A. I just want to basically go back and reference that the background of the invention is really -- it states very clearly when it comes to medical issues that it's the total health care functions for an integrated -- for they have not integrated

important elements of the total care into the system, and that's really where he talks about -- that's the linkage of the medical treatment statement.
Q. This is --
A. This is in the patent on column one. It is line 36, I believe, however, such systems have not hitherto featured the total health care function for they have not integrated important elements of total health care. That's all I wanted to make sure.
Q. Why is that important?
A. Because when we talk about medical treatment, that's the concept. He's talking about medical treatment. That's the concept. It is not the concept of linking a payment system to a medical, to an insurer, because the payment system is only a portion. It's a declared portion that is not -- it's out there, but it's the integration of the care model.
Q. That's important in this context?
A. Well, when Andy refers to -- when this statement refers -- the suggesting that the claims matter of this application which is directed to the aspects of medical treatment, I just wanted the medical treatment to be understood as not the payment of claims but the process of putting the care management, comprehensive care management system together.
Q. Why is that important to the 105 patent?
A. Because that's what Andy claims is in the background of the invention is the distinguishing factor.
Q. Is that described anyplace else in the 105 patent?
A. I think it's described in the vision. I should say the abstract. It's a fully integrated and comprehensive health care system that includes the interconnection and interactivity of patient health care provider. Other financial insurance companies utilization reviewer and employer so as to include within a single system each of the essential participants to provide patients with complete comprehensive pretreatment, treatment, and post treatment health care and predetermined financial support thereof.
Q. That's important to your invention?
A. That's the comprehensive, the vision.
Q. Is that what you mean by a health care management system?
A. Where are you referring to now?
Q. I'm not referring to anyplace. You use health care management system all over this patent.
A. I have to be shown a specific -- because I think it takes the global view and then it breaks it down to preferred practice.
[Cummings:2002, p. 127 l. 12-25, p. 128 l. 1-25, p. 129 l. 1-13].

Converting such a vision to an actual system is of course a difficult task and one not enabled by the specification. The specification of a future utopia and collecting all possible prior art seems impossible. The `105 patent does not provide any resolution. No specific technological advance was specified in the application. It is no wonder that Singer, when investigating prior art, restricted himself to fully automated systems.

5.1.2 Symptoms are Distinct from Diagnoses

The distinction between symptom and diagnosis is initially stated clearly, even though it critically effects the validity of the `105 patent.

> "Symptoms would be things that the patient tells a doctor' ... `and physical manifestations that the doctor actually observes"
>
> `A diagnosis is the point at which you are able to say – categorize the symptoms within the Diagnostic Related Groups"
>
> C:`.... the government has put together or the CPT codes or the ICD-9 codes where you are able to code the problem, medical problem into an acceptable category'
> Q: `So the diagnosis is the conclusion of the doctor?'
> A: `Right' Q: `So the symptom and the diagnosis are two different things?' A: `yes'
> Q: `But CPT, that's various procedures? A Right. Q: That's not a symptom, correct? A: `No, That's a treatment. That's a payment methodology and so forth. Basically, get it down to a diagnosis related group' <(DRG) used for billing>. `stomach ache' versus `ulcers' . [Page `160].
>
> Symbolic of symptoms does not mean symbolic of diseases. [Page 182].
>
> Treatment is two steps removed from Symptoms [page 184].

The intermediate step is clearly obtaining a diagnosis, a task that Cummings here, but not in the patent, assigns to physicians. However, the requirements for diagnostic tests needed to produce signs and the role of the medical history in that process are not well elucidated:

> Identification of symptoms for diagnosis is a physical exam process.

This statement, offered when going through the claims conflicts with his initial, correct explanation. See the definitions for Symptoms, Section 3.1 and Signs, Section 3.2.

"Q: ... what's the difference between data symbolic of symptoms and symptoms for diagnosis?
A: They're similar.
Q: Are the same thing?
A: could be the same thing but not all – yeah." .... , but some are text statements. [p.311 l.17-21].

Actual systems require clear codes, typically ICD-9 based, for treatment advice and reimbursement decisions

5.1.3 Defining a Smart System

The technology, role, and requirements of the `smart systems' that are hypothesized in the `105 patent to bridge the gap from Symptoms to treatment is not well understood.

> Q: `So the system of Claim 1 is a smart system, correct?'
> A: `It's part of the utilization. Right'. A: `yes',
> Q: `What is a smart system?'
> A: A smart system is capable of managed artificial intelligence or rules based'.
> Q: `What is artificial intelligence?'
> A: `Pattern analysis'.
> Q: `Okay. What is Pattern analysis?'
> A: `The ability to keep a system learning as you add more data'. Insurance company sets the rules.
> [Cummings I:2000, pp. 161-162].

We have provided our definitions for `smart system' and `artificial intelligence' in Section 3.15 and 3.17, concepts that an inventor in the field should be familiar with if he intends to teach others how to implement a system that he has not built himself.

5.1.4 Smart Systems are Publicly Available

To bridge the lack of understanding of smart systems, Cummings makes the assumption that they are publicly available. However, he has never attended a meeting, nor is a member of the society where researchers and developers work in that arena.

> "Q: Did you look for any kind of a smart system at the time, prior to filing the application?
> A: Basically, we did a search.
> Q" When you say, "we did a search, " who did a search?
> A: basically, I asked for a search to be done.
> Q: Asked who? Andy Haskell.
> Q: and he did a patent search; is that right?
> A: Yes.
> [Cummings II:2000, p.219 l. 10–18].

Cummings' knowledge seems limited to what is made available via marketing blurbs. In responding to a query about how to obtain `smart systems` he opines:

> A: Use experience, learning, factor analysis, literature review to create the smart system rules. Expect there would be plug-and-play resources, as from NIH. Use focus groups.
> Q: How much work is that?
> A: Work would NOT be significant. Use consensus.
> [Cummings:2000 II p.276, 277].

To substantiate that opinion, Cumming's mentions his experience in statistical education, working with doctors over many years.

250 doctors at Huguley.
Medicine is dynamic.

But none of that work involved building systems as envisioned in the patent. Cummings had involvement, although again, not in actually building systems that provide advice about healthy life styles. There is quite a difference in scope and in risk from telling people how to behave versus determining medical interventions. Reliability and correctness become issues, often requiring FDA certification.

Q: how to test?
A: Problem is compliance.
[Cummings III:2000, p. 324-327].

The response indicates that the experience is based on creating advice for patient's behavior. When queried further the issue of liability arises, which is one of the reasons why research into health care computer systems involving medical practice is progressing slowly and requires much precision, care, and validation.

Q: `When the system is implemented and it's at the hospital, does that system actually work at that point. You have created the rules.'
A: `Sure, it works.'
Q: `And have you ever seen such a system work, such a smart system?'
A: `I have -- limited'.

Cummings then mentions systems for pre-certification and pre-authorization, systems which existed prior to the application for this patent, and recognizes that there is a:

A: `Liability issue. Big job, yes'

By considering our definition, we can clearly see here that nothing was invented, nothing suitable had been built, and nothing was available to be integrated into a health care system.

Kaliski [Kaliski:2002], in defending the validity of the `105 patent when faced with this issue is forced to state that `any computer system is smart' (see Section 5.5.3). Such an opinion invalidates the patent, since now all computer systems in health care would be equally smart, and any of the many systems that included the steps claimed, becomes invalidating prior art.
.

5.1.5 Factor Analysis can be used

Cummings claims that factor analysis (see Definition 3.21) can be used to drive `smart systems'.

A: Yes, I knew how to do it.
Q: Okay. How do you actually take symptoms and come up with a proposed mode of treatment? How is that actually done?

A: Through pattern analysis.
Q: How is pattern analysis done?
A: Basically, where you have the best outcomes from an experience of employees and you're able to factor-analyze what are the best outcomes for treating various conditions.
Q: And you knew about pattern analysis when you filed the application? Pattern analysis?
A: Yes. It's statistical concept.
Q: And you knew about that at the time you filed the application?
A: It's factor analysis, is what it is.
Q: I guess you knew about factor analysis at the time you filed the application?
A: I did.
Q: And at the time you filed the application, the best way to come up with a best practice mode of protocol was to do factor analysis, correct?
A: Right
Q: That's what you contemplated at the time you filed the application.
A: Yes.
Q: And how exactly would this factor analysis be conducted? And, again, I'm talking about at the time you filed the application. How did you contemplate actually doing this factor analysis to come up with this system to determine a proposed mode of treatment based on symptoms?
A: Basically, through loading large databases of history into the computer and really doing an analysis process.
Q: How would that analysis be done?
A: The first step you'd do is focus groups with doctors on particular symptoms, finding out what they believe is the best, and utilizing literature and then comparing that to actual practice as you gathered the data.
And – And keep refining that. So that's why the smart system.
Q: So the best way of coming up with this system to determine proposed modes of treatment based on symptoms was to do factor analysis, to look at large databases, to get focus groups with doctors and to correlate the symptoms to proposed treatments, correct? Is that correct?
A: It was a statistical process.
Q: Statistical process.
A: Right.
[Cummings II:2000, p. 206, p. 207, p. 208 l. 4-7].

When deposed he realizes the difference of scale from his experience and the problem that would arise when deriving treatments from symptoms, or even just obtaining diagnoses from symptoms.

A. It is far from routine.
Q. It would be quite difficult?
A. Yes, it would be difficult.
[Cummings II:2000, p. 208 l. 19-22].

Increasing the number of symptoms to about 7,000, the number of diseases to about 12,000, and considering the interaction of even two diseases, creates a computational problem, since the products of the symptoms and diseases forms the base. More diseases that interact with each other further multiply the problem scope. Cummings is well aware that much of our population has multiple diseases, and terms that the "Floridization of health care."

> Q. If you can summarize your basic speech in a minute or so, would you mind doing that for us?
> A. Sure. My basic speech is that we're facing a different era, which we've called the Floridization of the globe which, in essence, is in the year 2000 18 and a half percent of the people in Florida turned 65 or older. That's the first time that's happened in a state or -- but it's going to happen around the world. What has happened is the Sandia Labs have called us the Floridization of the globe, and they show that Italy comes next, Japan next, and by the year 2023 all of the States will be in the same condition as Florida is today and Central Florida, 18 and a half percent over 65. What that does is change the health care equations. It changes it from an acute care solution demand to a chronic disease demand, and this is illustrated in the rise of chronic disease affecting the costs of the delivery of care for Medicare patients which shows that -- the congressional record shows that 68 percent of the people of -- the costs of Medicare is for people with five or more chronic conditions, and that is an escalating fact of aging. The difference between acute care, which was the medicine that brought us the solutions of moving the age expectancy in the first of the 20th century from 45 years to the end of the 20th century to 78 years was solving the contagious diseases. Now we have the chronic diseases. The contagious diseases can be solved with an episode or a vaccination or public health strategy, but the chronic diseases are lifestyle solutions, and you must create a care around the patient that supports them throughout a continuum. My father has diabetes, for instance. You don't start managing him when he crashes in the emergency room, or you have huge costs. You manage him in the morning, what he eats, when he takes his medications and all that. In that situation the core shifts because the problem that we had in managed care was a false assumption that all we need to do is change the incentives of the doctors by changing the way they're reimbursed, but, in fact, they didn't have the systems or the resources to manage and continuum of care. They only -- they've been trained episodically. When the problem was episodic, they were really good. When the problem is a continuum, they don't have the resources, they don't have the systems, and they don't have the solutions. What happens in the acute care model is the focus is on the physician and the staff. The patient is just treated as an object. You make them comply because you have total control. In the new model of chronic disease, the patient gets more than 70 percent of their own care. They are their own primary care giver, so we call that the age of the pro-consumer where I'm my primary care giver, I'm my provider, and I consume specialty care. In creating that continuum is what we think the future is about.

Q. In the context of your speech and what you think is going to be the future of health care, do you envision, you know, computerized systems that need to be developed to support that?
A. Yes.
Q. What kind of systems would they be?
A. Basically, you know, where they are available. Point of care systems so you can provide the care at the point of need for the patient.
Q. What do you mean by point of care system?
A. Well, a system that provides you the information and the capabilities of delivering care in the setting that empowers the patient so you can integrate the care. Right now one of the huge problems we face is that a person who has ten chronic diseases or more has 49 prescriptions, 13 different doctors, and goes to those doctors 37 times a year on average. The Gallop research shows those people tell us they get different -- on the same set of information get different conclusions about what their problem is, get overlapping tests, and get no coordination of care, so that has to be addressed.
[Cummings:2002, p. 19-21].

The effect of moving to the actual scale needed for healthcare is that the effort becomes many orders of magnitude larger, at least a thousand times. To support such the computational problem would need quality data on a population that is larger than the population of the world. Even highly restricted analyses are immense [Framingham:2001].

If Cummings had actually tried to build such a system, he would have realized its impossibility. Now this solution is merely part of his vision.

Q. Do you know how to use factor analysis?
A. Yes. I used factor analysis.
Q. Is that a statistical tool?
A. Yes.
Q. Do you know about P values?
A. Yes.
Q. What are P values?
A. Boy, you're sending me back to -- is this a test? P values are probability values.
Q. Do you know about degrees of freedom? Have you used that term?
A. Yes.
Q. What does that term mean to you?
A. Degrees of freedom is the amount of choice that you have with any given system. It is the number of choices you have minus one. For example, if I gave you a multiple choice question that had A, B, C, D, E choices, you would have four degrees of freedom. If I gave you a question that said name the first president of the United States and there was only one right answer, you would have zero degrees of freedom. That's my understanding. Like I said, I'm not an expert.

Q. If you were standing on or sitting in your car on a street corner at a stop light, how many degrees of freedom would you have then?
A. It depends if the light is red or green. If the light is red, I would have only -- I would have zero degrees of freedom because I can only turn right, which is one option minus one. If the light is green, minus one, so I would have two degrees of freedom unless I could back up. That might give me a little more.
Q. In the statistical sense do the degrees of freedom relate to variables?
A. I'm trying to think. Are you talking factor analysis?
Q. No, just in general.
A. Do degrees of freedom relate to variables? They can in a testing format. They will tell you if one of your variables is the right answer to a question. Let's say one of your variables is you're producing a test and you've got an answer within that test and that becomes a variable, then there may be five right answers which would mean four degrees of freedom within that variable or there may be one right answer or zero degrees of freedom within that variable. So it can have that influence, but, again, you really have me skating on territory that is -- wow, I'm digging hard to recall.
Q. When you did your dissertation, did it address any degrees of freedom or a statistical system with variables in it?
A. Yes.
Q. How many variables were involved in the topic for your dissertation?
A. I believe it was a matrix of 345 by 144, I believe. It was 148, one of those. It was somewhere over 140.
Q. Three something by --
A. So I had 345 variables on 148 or 49 subjects.
Q. What generally was the application for those variables?
A. That was a study of the factors of church growth among Caucasian churches in North America for the Seventh Day Adventist Church.
Q. Did you do any computerized analysis on those factors?
A. Yes.
Q. Was it a computationally intense study?
A. Very. I mean, there was a lot of computations in the sense that the computer did them all, but it ground a long time to get them through. It was basically factor analysis applied to those variables, boiling those variables down to factors.
Q. So you have some experience with multi-variable symptoms in factor analysis?
A. Yes.
Q. Now, when you compare the number of variables in your study for your dissertation to the number of variables to apply to a health care management system, what is the comparison there?
A. There's a lot more complexity in a health care management system.
Q. In order of magnitude maybe?
A. You know, there's a lot on the order of magnitude, yes.
Q. Ten times as much? 100 times as much?
A. You would have to get somebody to sit down who knows the field and suggests that.

Q. Is it fair to say that in computing statistical systems that as the number of variables increases linearly the computation will increase exponentially?
A. I don't know if it's fair to say it increases exponentially. I think it depends on the statistical tool you use to organize the variables.
Q. In your dissertation study what kind of statistical tool did you use?
A. I used multiple regression and factor analysis.
Q. What kind of computer processing system did you use?
A. I used the university's system.
Q. Which was the mainframe?
A. Yes, it was a mainframe.
Q. A mainframe is a fairly large computer?
A. Yes.
Q. Not like a PC?
A. Well, today our PC's would surpass the mainframe by tons. It was a mainframe, but it was not a horse.
Q. How much data was used for your study?
A. Like I said, it was 145 subjects with 340 variables on each subject, so that was the size of the matrix. But that's why we used factor analysis to organize the variables so that you could shoot vectors through the data to find out what correlated, and then you had to interpret it because factor analysis is both a scientific process and an art, very much of an art.
Q. It took a long time for the computer to crank through the calculations that you needed?
A. It took a while.
Q. Have you ever built a system that was able to select proposed treatments based on symptoms?
A. I have basically been involved with disease management most recently. Are you talking about -- put that in a time frame. Are you talking about now?
Q. Anytime.
A. Basically been working on various things along that line. One of them is disease management approach in which you basically -- the pattern of treatment that you put together for, like, diabetes patients, and then you have -- you customize it to the particular patient. [note, here the diagnosis is known]
Q. You're working on that now?
A. We actually implemented that and saw the results of that kind of management when we were actually running a Medicare demonstration project.
Q. But that's management. That's not generating a treatment scenario based on an input of systems?
A. Well, it's chronic disease management, so it's taking the conditions that the patient has and actually saying what's the best course of action to support them on and updating the symptoms, so you're able to gauge how they're making progress or whether they are in danger and needing intervention. Disease management is a field that's really in need of that kind of best practice.
Q. Well, in that system that you're referring to, what's it called?
A. We don't have a name for it. It's just our disease management program. [Cummings:2002, p. 141-146 l. 1].

This discussion of factor analysis, a method proposed to fill the discontinuity starts out with a nice example, but when some complexity are introduce that will arise when using this methods for comprehensive processing of symptoms, the responses reveal that scaling his technology from a thesis project or an HRA effort (see Section 3.21) to the level needed for comprehensive health care support not been addressed by Cummings.

5.1.6 Health History

Health history comes from the patient, includes medical history.

> A. Lifestyle elements and medical history, lifestyle risks.
> Q. What specific lifestyle elements and what specific medical history?
> A. I basically -- the lifestyle elements, things like I described before, like smoking, exercise, weight, the primary morbidity factors.
> Q. What are the primary morbidity factors beside weight, exercise --
> A. Smoking.
> Q. -- and smoking?
> A. Stress, probably, is the other factor, depression.
> Q. Drinking?
> A. Could be, yeah.
> Q. Alcohol consumption?
> A. Right
> Q. And so at the time the application was filed, you thought the predetermined items of medical history that should be included for the system of -- the method of Claim 85 would be smoking, weight, stress, alcohol consumption, correct?
> A. (Nods head)
> Q. And what about for medical history? What are the items of medical history that you contemplated would be best included in the predetermined items of medical history for Claim 85?
> A. A lot - a lot of the normal medical history questions that you deal with of -- have you had, you know, prostate cancer? Have you been hospitalized? What medications are you allergic to? Those kinds of things.
> Q. Have you ever had diabetes?
> A. Right.
> Q. Have you ever been unconscious before?
> A. Yeah.
> [Cummings: 2000, p. 277 l. 23-25, p. 278, p. 279 l. 1-11].

5.1.7 Manual processing steps are covered by the patent.

The author of the `105 patent presumes that his patent also covers manual processing [Cummings: 2002, pages 142-145]:

> "Well, I think if you read through it, it also says it could be manual. So there is manual capabilities, as well as automated capabilities.

Q: Okay, Well --
A: Or automated --
Q: So Claim 1, to you, covers both manual systems and automated systems, correct?
A: Right.
Q: Okay. And a manual system does not have electronic communications between the patient, health care provider, bank or other financial institution, insurance company, utilization reviewer and employer, correct?
A: I think it's -- that's a technical decision I think that, you know, the telephone is a manual system, but it can be utilized with some automated properties. So it can be technically -- so I'd say that with that qualification, fax, telephone, those require certain manual -- whereas a computer's all automated. " ;
"In the patent process, there is data sending and there is human intervention" responding to "do you envision that possibly being done with people talking to each other on the phone": "In a primitive situation if necessary. Could be. I don't really -- the vision is to get all electronic"

Since the vision is broad, and could indeed encompass any prior or current healthcare system that we must take specifics from the claim section. However there is no indication of manual processing in the claims, nor in the prosecution history, nor in the prior art provided.

5.2 Singer:1990 Quality Assurance

Dr. Charles Singer is a consultant to Allcare in Health Care Information Technology. We received material provided by Mr. Singer on Quality Assurance [Singer:1990]. These documents describe fairly the need for quality assurance and provide in more detail a vision congruent with that presented by Cummings in the specifications of the `105 patent. Quality assurance is the central goal of Utilization review. Singer also had a role when the `105 patent was being developed in assuring Allcare and, indirectly, Cummings, that `105 patent did cover any prior art.

[Singer:1990, pp. 12, 3, 58, 52] defines Quality Assurance as a process matching our use of Utilization Review (see Definition 3.9); inputs include diagnoses, laboratory tests - resulting in triggers (we use the term sign - see Definition 3.3). It is a retrospective function. Claims data are inadequate for that purpose.

[Singer:1990, p 41] also describes `Utilization Management', the function that we call Cost- Effectiveness Review (See Definition 3.10) . `Utilization Management is defined as a distinct discipline from Quality Assurance, and focuses solely on lowering costs. An example of Utilization Management is pre-authorization of inpatient services.

The term `Symptom' does not seem to appear in Singer's work at all.

5.3 Singer Expert Report [Singer:2000]

The expert report submitted by Singer in connection with the 1990 Allcare case vs. Cerner et al. [Singer:2000] describes fairly the disjointed state of the Health care delivery industry in 1990 -- a situation that has not improved much since. He recognizes that "the `105 patent was at the time a valuable contribution in establishing a vision and framework for improving the American healthcare system" [p.5]. He agrees further with the patent "that a reasonably complete record of the patient's medical and insurance history" is required. None of that section addresses the claims of the `105 patent. In Section III Singer states his understanding of the law. In Section IV his report deals with prior art.

5.3.1 HELP is not invalidating prior art.

Singer's opinion is that the HELP system [Gardner:2000H] (see Section 4.4.1) is not a comprehensive system, as stated in the preamble of Claims 34 and 85, and that hence HELP does not represent valid prior art. Of course, a system containing only the elements in the body of Claim 34 or Claim 85 would not be comprehensive either.

For instance, on page 8 he states that "the `105 patent en*vision*s a more complete and comprehensive patient record, similar to the system Mr. Gardner *hope*s the HELP System will become". I do not know when Reed Gardner's or his predecessor, Dr. Homer Warner's hopes started. If we allow a *vision* to be patented, we should allow a *hope* to be prior art.

No comparative claims chart is provided, Mr. Singer relies on the specification in the vision.

Singer also faults the HELP system as not taking care of outpatients and not performing payment services. Other systems within the LDS systems obviously did perform those tasks. If Allcare's urged claim construction is adopted, then the HELP system (including the overall services at LDS) inherently should include all of the features of the claims. The '105 patent could not be built as a tightly integrated single system, as Singer claims is necessary to satisfy the `105 patent. A hospital will always be disjoint from a bank.

If we were to accept that manual processes are covered by the `105 patent (see Section 1.1.3), then we would have to revisit the systems at LDS, including the Help system.

5.3.2 Beth Israel, Brigham and Woman's Hospital (BI)

The Systems at Beth Israel, Brigham and Woman's Hospitals (BI) are not invalidating prior art. Singer's opinion is that the BI systems [Bleich:2000] (see Section 5.3.2) is not a comprehensive system, as stated in the preamble of Claims 1, 4, 34, 52, 55 and 85, and that hence BI does not represent valid prior art. Of course, systems containing all elements of Claims 1, 4, 34, 52, 55 and 85 would not be comprehensive either. No comparative claims chart is provided.

Singer notices specifically that no payment system is included. Reimbursement does occur at BI, of course, but it is performed by remote subsystems, interfaced, but not included in the systems that Dr. Bleich was asked to describe. The `105 patent, since it is a distributed system according to [Kaliski:2002] (see Section 5.5), allows communication with insurance companies at remote locations. This criticism violates the spirit of the integrating intentions of the `105 specifications (see Definition 3.22). Furthermore, if all systems need to be that tightly integrated, then the case against TRIGON would be void, since TRIGON interoperates with many other systems in carrying out its tasks.
Singer deduces that the `105 patent envisions open interconnection, not proprietary communication. At the time the patent was drafted the Internet was not available, only in 1993 were the domains .com, .org, and .net defined by NSF. The provider at that time of open services for the academic community, and commercial registration came later.
All prior systems outside of academia at that time had to use proprietary technology, and TRIGON still uses proprietary communication, so by that distinction TRIGON systems do not infringe.

Singer also faults BI for not having complete medical records available at all locations. We now fight the confusion of what a medical history contains (see Section 1.4). The cited `105 claims, nor the specifications specify when a Medical History is deemed to be complete. Deriving such stringent requirements from the preamble term `comprehensive' will invalidate the `105 claims themselves. Singer further faults BI's Medical History system in that the outpatient Medical History is only available for 15 months and lab reports only available for 6 months. Since the `105 system was never implemented, we can only guess how much of a patient's history would be included -- it is unlikely that many physicians would enter historical information beyond what is needed for reimbursement of claims. If BI fails Singer's test, so does the claims section of `105 and so does TRIGON. There is no significant amount of patient's history included in the TRIGON system, it only has reimbursement claims data.

Even though we object to much of Singer's reasoning, we would likely come to the same conclusion that the BI do not represent invalidating prior art, since the BI systems do not and cannot perform the miracle that is required to bridge the disconnect discussed in Section 1.1, and here required in Claim 1(d), Claim 4(e), Claim 34(d), Claim 52(c), Claim 55(d), and Claim 85(e) respectively. If we were to accept the construction urged by Allcare, i.e., that manual processes are covered by the `105 patent (see Section 1.1.3), then we would conclude otherwise.

5.3.3 The OPTIMED does not represent invalidating prior art.

Singer's opinion is that the OPTIMED system [Wellman:2000] (see Section 4.5.5) does not have sufficient automation to qualify as relevant prior art. It used, at least at that time, telephones for communication, while "The preferred embodiment of the present invention includes the integrated connection and interaction of the patient, healthcare provider, bank and other financial institution, utilization review/case management ... " [page 11] such "electronic communication means as required by the patent". This statement is in conflict with [Cummims:2000, pp 194-196].

Singer also notices that no payment system is included. OPTIMED is only a subsystem, purchased by companies as Blue Cross to carry out a specific task. Reimbursement of health care costs is their business, but it is performed by other interfaced subsystems. This criticism violates the spirit of the integrating intentions of the `105 specifications (See Section 3.22). Furthermore, if all systems need to be that tightly integrated, than the case against TRIGON would be void, since TRIGON interoperates with many other systems in carrying out its tasks.

No comparative claims chart is provided.

If we would be limited to reviewing only the OPTIMED subsystem, we would also come to the conclusion that this subsystem does not invalidate the comprehensive, if fictional, `105 system. If we are to evaluate prior art in respect to a patent, as `105, that represents a vision of a comprehensive approach, then we'd obviously have to assess systems in which OPTIMED plays a role, not just the OPTIMED module itself. If OPTIMED's capabilities become an issue, then a comprehensive comparison will be needed.

5.3.4 The Review Provided by Krieger is incorrect.

Paul Krieger, an expert in Patent and Trademark law (in a prior action relating to the '105 patent), reviewed o.a. [Gardner:2000H], [Bleich:2000], and [Wellman:2000], as described in Section 5.9. Singer considers that the Pritchard patent [Pritchard:1985] (see Section 5.12) reveals the Bank-One system, so that Krieger's contention that Bank-One should have been presented to the examiner is moot. However, the Bank-One is a system, which can incorporate indeed the Pritchard and other patents. We are here comparing systems, and when Singer seeks comprehensiveness, all of a system, not just an embedded novelty must be presented.

There is again the question of missing functions in the Bank-One system versus the comprehensive intent of the `105 patent. Again, the Bank-One system operated in settings where all needed functionality was present, and cannot be faulted for not including capabilities of a system that was never built.

Singer observes that `adjudication' is not the same as utilization review, faulting the Bank-One brochure for incorrectly characterizing `utilization review', a quality control process that singer is well familiar with, and matches our definition (see Definition 3.9). Adjudication refers to the cost-effectiveness review process carried out at insurance companies (see Definition 3.10). However, utilization review was known as an adjunct to adjudication in an insurance company.

5.3.5 Singer insists that the `105 patent requires full automation.

Singer makes a strong point that systems that use of any manual steps are not invalidating prior art. That point is consistent, in fact necessary, given his work at Allcare around 1990, where he did a study searching for prior art. As stated in [Conner:2000, pp.35-38],

Singer, according to Conner:

> ... looked in all of the places that he felt, at the beginning of our relationship, such prior art might exist, if it did, and was satisfied that it didn't.

Singer, a knowledgeable expert, is likely to have been aware at that time of the efforts he is dismissing, say those nearby at Beth Israel (see Section 4.4.3), at LDS, at Optimed (see Section 4.5.5), as well as well publicized efforts at Technicon (TDS) -- see Section 4.4.5, at the Harvard Health Plan – see Section 4.4.2, and at the many sites ([Wiederhold:1976] lists over 100 efforts already at that time).

The holder of the `105 patent claims not to have been aware of any of them, [Cummings VI:2000, p.126-129], stating that he fully relied on Conner to check for prior art:

> Q: (Patent office) "just did searches of patents, did not do searches of what vendor systems there were or what other hospitals were doing, what insurance companies were doing, did they
> A. My background and assumption on that was Bill (Conner) was with the managed care side.
> Q. So you were relying on Bill Conner for the expertise to determine whether or not this was novel; is that correct?
> A: I was relying upon Bill and the way he worked with the patent attorneys with John and Andy to do that. and when Bill asked for a search to be done, I assumed it was a literature search, because a couple of searches were done. So I assumed it included the literature as well. But Bill's knowledge of the HMO systems and so forth was far – he had been in the business, so his knowledge of that and the technology people he had and, you know, the fact that he had brought in a guy from, you know, the Tandy organization and his relationship with that and American Airlines and those folks, that's really where I saw the contribution and the expertise that I relied on". pp.130. l. 2-24

and

> "My role was to focus on the invention" p.131 l. 18.

It is a bit hard to accept that an inventor should be innocent of all prior art except of patents retrieved during patent examination. Note that all those patents are also limited to fully automated systems, even though their scope is much more limited than the `105 specification.

5.3.6 Singer expects open communications.

If patients are to communicate freely, as is the intent of the `105 specifications, an `open network' is required.

> The (`105) system envisions an environment in which many of the entities in healthcare would be able to inter communicate, in a manner similar to how the Internet has evolved to a more open environment [Singer:2000, p. 6].

Because of the risks to patient privacy and financial integrity, few health care systems have implemented open networks. Given the state of communication when the patent was applied for it would indeed be hard to find any open network that would qualify. The Internet was not yet `open' in 1990. Trigon does not operate an open network. I believe only the Healtheon approach qualifies by that criterion.

5.3.7 Summary of Singer:2000 Report

Singer bases his understanding on full automation of the comprehensive vision presented in the specification. The vision he presented in his 1989 work is similar to Cummings, but focuses on Utilization Management, i.e., the reduction of heath care costs, the central focus of his consulting career [Singer:1990]. He finds fault with all prior submitted art because they failed to support that vision fully. Comparing an existing system with a vision will always favor the vision.

Of course,- TRIGON does not support the full `105 vision either, it only arranges for reimbursement of the delivery of episodic care. For instance, Singer observes that the system contemplated in `105 includes a reasonably complete history of the patient's medical and insurance history, matching our definition (see Definition 3.7). But if that must be the case, then TRIGON cannot infringe on `105, since TRIGON only stores reimbursement claims that it received for reimbursement, and hence has only a reimbursement claims history (see Definition 3.8).

5.4 Singer:2000 and 2002 Depositions, and 2002 Report.

5.4.1 Singer 2000 Deposition [Siunger:2000D]

Cummings and Conner indicate that in the 1989-1993 time frame Singer did a search for prior art. Singer obviously focused on the specifications instead of on the narrower claims:

> to be honest with you, I looked at the claims probably spent – those charts, and probably spent 5 to 10 minutes on them, and then decided that I would prefer the language of the patent directly. I found the charts sometimes a bit confusing, harder to read, than just reading it directly (p.140 l.3-9).

5.4.2 Singer takes an alternative approach

In [Singer:2002. pp. 75-77] a new interpretation of the patent is presented;
Instead of symptoms leading to treatments, treatment entry leads to alternative treatments, and symptoms are ignored:

... my interpretation of this is that the physician or the person providing the care is entering the proposed mode of treatment. Q: Okay. All right. .... You described your understanding of this section to mean that the physician would – actually proposes "This is what I'm going to do," and the system might respond by saying, `Well you might want to also do theses other things.' That's what you mean right? A: Right. Q: Okay. And then I'm asking you, that would be different from the physician simply putting in the symptoms, say the patient's got a fever, complaining of stomachache, and then the system suggesting a proposed mode of treatment for that? ... A: If your question is, if the computer diagnosing and deciding what to do, those systems are again extremely rare with the following caveat. A lot of times the physician will make a diagnosis and decide `I want to do a knee arthoscopy' or I want to do whatever ' and system may come back, because it has access to the patient history, and say, `Oh, by the way, the person's allergic to this. Do you want to do this instead' or whatever. So the issues is, is that the physician taking the first initiative, but the system may still suggest treatment, may suggest even diagnosis, but the key is that the physician start the process by entering a proposed mode of treatment.

This interpretation conflicts with the specification and the claims of the `105 patent. It also conflicts with statements made earlier in his deposition that, albeit rarely, an expert system would translate symptoms to diagnoses
[p. 73].

5.4.3 Singer 2002 Report.

Charles Singer submitted a brief letter in support of the Allcare Action Vs. Trigon. It provides a sketch which purports to define the match of the `105 patent and TRIGON operations. It is at such a high level that it can equally well apply to much of the prior art and current systems.

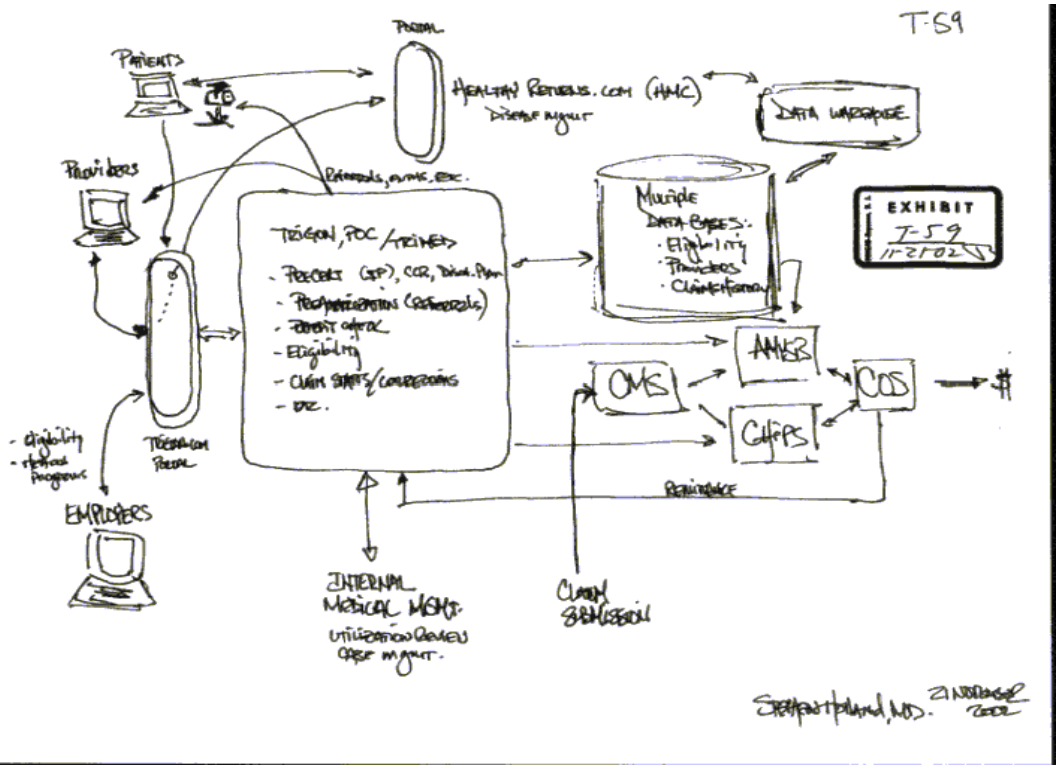


Figure 3. Singer Sketch comparing the `105 patent with Trigon's systems

This sketch does not identify the matching `105 elements, and differs greatly from the figure provided in that patent. It should differ even more, since Singer fails to provide a Terminal for the Internal Medical MGMT performing utilization review. They also initiate manually telephonic contact with the provider to help adjudicate payments. But such linkages would be in conflict with Singer's view that the `105 patent represents a fully automated system.

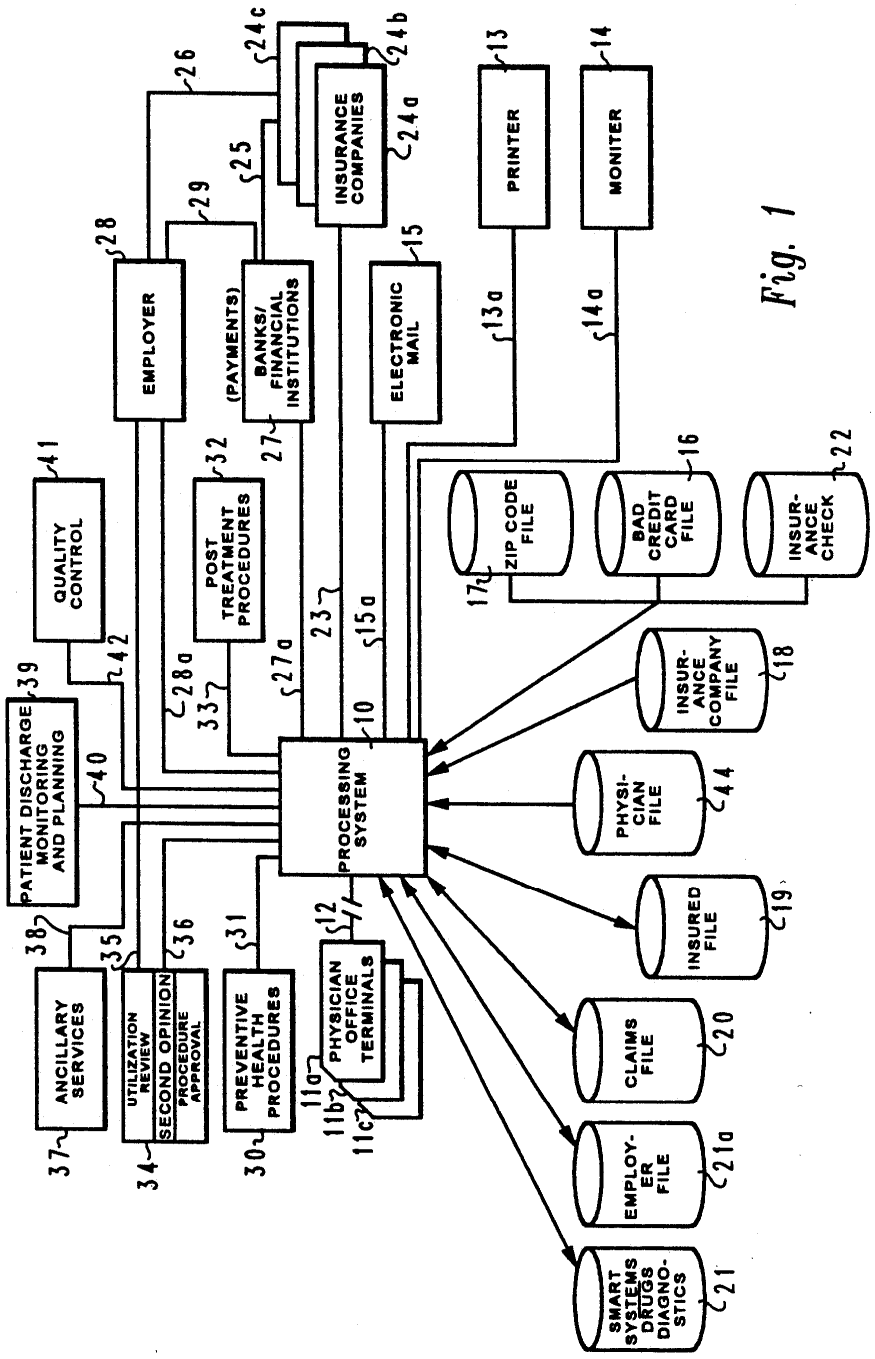

PROCESSING SYSTEM
10
EMPLOYER
28
INSURANCE COMPANIES
24a
BANKS/ FINANCIAL INSTITUTIONS
(PAYMENTS)
27
ELECTRONIC MAIL
15
PRINTER
13
MONITER
14
ZIP CODE FILE
17
BAD CREDIT CARD FILE
16
INSUR-ANCE CHECK
22
INSUR-ANCE COMPANY FILE
18
PHYSI-CIAN FILE
44
INSURED FILE
19
CLAIMS FILE
20
EMPLOY-ER FILE
21a
SMART SYSTEMS DRUGS DIAGNO-STICS
21
PHYSICIAN OFFICE TERMINALS
11a
11b
11c
12
ANCILLARY SERVICES
37
UTILIZATION REVIEW
SECOND OPINION
PROCEDURE APPROVAL
34
PREVENTIVE HEALTH PROCEDURES
30
POST TREATMENT PROCEDURES
32
QUALITY CONTROL
41
PATIENT DISCHARGE MONITORING AND PLANNING
39
40
42
35
36
31
38
26
24c
24b
25
29
23
15a
13a
14a
27a
28a
33

Fig. 1

Figure 4. The overall structure of the `105 patent system (Figure 1.)

5.5 Kaliski:2002

Professor Kaliski, of Cal State San Luis Obispo brings his knowledge of Computer Science to bear on this health care system.

5.5.1. Kaliski draws specific conclusions from a generalization.

Kaliski recognizes that the system sketched in the specifications is a `Distributed System':

> A person of ordinary skill in computers would have understood in 1991 that a distributed processing system is characterized by a set of interacting computers or databases situated at different locations. In such an environment, entry of commands or data in one computer can and does impact the data processing and/or storage activity of other computers within the distributed system [Kaliski:2002, p. 4].

We agree with that observation. Distributed Systems have been known in Computer Science for many decades, the classic text is [Tanenbaum:1981].

Distributed systems can have an infinity of configurations. The claims in `105 are much more limiting. As detailed in Claim1, specifies input of a patient identification, and Claim 2 augments that with input of symptoms. No other source of information is specified, outside of medical history (see Section 1.4 and loading of databank tables, all claim elements dealing with communication). [Kaliski:2002, p .. pp]. Kaliski opines that since the system specified in `105 is a Distributed System that all general aspects of Distributed Systems can be assigned to this patent, [Kaliski 2002D: p.124],

A. Well, remember, this is in general a distributive computing environment so it's very hard to say where the input's being done, where the part that's supported all of these three functions is physically located relative to that.

including at the medical director's site [p.84] . That such a generalized system then might infringe in TRIGON's operational systems is an unwarranted extrapolation

For instance, it is stated in [Kaliski:2002, p. 11] that it is natural to have a printer and keyboard at the Insurance Company's Medical Director's site, but nowhere in the specifications or in the `105 claims is such a device specified at that location. There are printer, display, and keyboard devices specified, but they are all located in physician's office. Specifically:

1. Figure 1 of `105 shows a printer and (sic) moniter as being attached to the processing system as units 13 and 14. In column 4, lines 14-21 the printer (13)

and monitor (14) are described as being in the physician's office `to facilitate observation and review'.

2. Figure 3 of '105 shows units 11a-c referring to a terminal, unit 66 to be a high resolution display, repeats unit 13 to be a printer generating reports 66a, 66b, 66c, and a unit 61a to be a personal or mainframe computer.' These devices are further described in the distributed environment section of the specification, column 7 lines 46 to 69. It states there also that the files need not be resident in the physician's office, indicating that the other units will be placed within the physician's office. This placement covers specifically the terminal 11a-11-c. The paragraph continues (line 55) with the costly, hence 'optional high-resolution display is preferably locate in the Physicians office to permit real-time display and visual review of relevant data, test results an the like.' The printer unit 13 was already described as being located in the physicians office above.
3. Claim 1(a) refers to an `input means', possibly a terminal for entering the patient's identification in the physician's office.
4. Claim 1(d) informs the physician through communication means, possibly via one of the terminals in his or her office, of suggested treatments and indicating those that may require utilization review.
5. Claim 2, dependent in Claim 1, also provides for communication of indicated ancillary services to the physician.
6. Claim 4(a) refers to input means for entering the patient's identification and for entering patient symptoms, also in the physician's office.
7. Claim 4(e) repeats Claim 1(d).
8. Claim 6 adds to 4(a) adds the requirement for entering predetermined items of medical history, also in the physician's office.
9. Claim 7 adds to Claim 4 that "said data input terminal is responsive to inputs there to enter into one of said data banks data severally identifying said predetermined plurality of persons", still in the physician's office. Kaliski [Kaliski:2002, p. 13] states: "Although there is no reference to a "data input terminal" per se in Claim 4, it is my opinion that a person of ordinary skill in the art of computer science reading Claims 7 and 12 would understand that the reference to said data input terminal is a reference to the input means of Claim 4(a)." We agree.
10. Claim 11 (not asserted in this case) adds that "said data input terminal includes provision for data entry from a magnetically-encoded medium." Since this card is carried by the patient, this claim reinforces our understanding that the terminal is located in the physician's office.
11. Claim 12 adds that "said data input terminal includes provision for data entry from a manual keyboard"' still in the physician's office.
12. Claims 16(a), 16(d), 21, 22, 26, and 27 repeat the terminal issues of Claims 4(a), 1(d), 6, and 7, 11, and 12.
13. Claim 17 repeats Claim 5.
14. Claim 19(a) and 19(e) repeat Claim 4(a) and 1(d)
15. Claim 31 (not asserted in this case) specifies entry of employer-derived information into a terminal at an unspecified location, possibly at an employer, "for entering data identifying each of a predetermined plurality of persons being on a payroll of an organization".

16. Claim 32 (not asserted in this case) specifies two terminals, one, as above, "at the location of a medical services provider for entering data identifying each of a predetermined plurality of persons being on a payroll of an organization; a second data terminal at the location of said organization" for (e) "for producing at the location of said second data terminal indicia indicative thereof and for permitting authorization for the excess to be made by said organization." An authorization for absorbing the excess of what an insurance company will allow as reimbursement for a claim is the responsibility of a medical services provider, as a Physician or a hospital.
17. Claim 33 includes a terminal for identifying patient's subject to workman's compensation. No location is specified. Such data is normally obtained from the patient in the physician's office or a hospital's emergency room.
18. Claim 34(a), 34(d), 36, 37, 42 and 43 repeat the terminal issues of claims 4(a), 1(d), 6, and 7, 11, and 12.
19. Claim 47 (not asserted) in (a) repeats the input means of Claim 1(a), includes (g) "symptom input means", similar to Claim 4(a), (h) responsiveness, as Claim 7, approval of charges, similar to Claim 32, (k) payroll deduction, (l) access to results of utilization review. The physical therapy services to be supported by this `105 claim can be provided by physicians, hospitals, or other ancillary medical services providers, but not by an insurance company.
20. Claims 52(a), 52(c), 52(d), and 53 repeat Claims 1(a) and 1(d), and 5.
21. Claim 54 adds providing indications of desired preventive health routines for the patient to the physician. No device is specified, but it seems reasonable that it would be located in the physician's office.
22. Claims 55 (a) and 55(b) repeat Claims 1(a), and 6. Claim 55 also specifies means for loading the program database tables, possibly for the claims processor programs. It does not specify if a terminal is used for this function. Any terminals needed can be located at the physician's office, since the specifications allow the files to be located remotely (see point 2 of this list above).
23. Claims 57, 62, 63 continue Claim 55 by repeating Claims 6, 11, 12.
24. Claim 65 (not asserted) continues Claim 55 and repeats 1(d).

There is no indication in the specification or any of the claims of `105 that any printer, monitor, display, or keyboard equipment is available for review in the premises of the medical director of an insurance company. We hence must assume that the patent intended the process of payment of reimbursement claims adjudication to be fully automated. Indeed, Kaliski in [Kaliski:2002, p.13] agrees that "In terms of what structure in the `105 patent supports the function of the input of data per the claims in suit, the Joint Statement shows that the parties agree that the structure is a ‘physician office terminal.’ ” We also agree with his further exposition about terminals, and their development. [Kaliski:2002, pp 13-15].

The fact that Kaliski is able to design a system that would include such facilities at other locations than the physician's office is due to his expertise, not based on an interpretation of the `105 patent.

> Using a terminal, Trigon employees can communicate with the Trigon system. [Kaliski:2002, footnote on p. 11].

Kaliski is clear when he says that:

> the medical director in the insurance company should also have a terminal. Because that's what you'd expect from a distributed system.

We agree that this is a requirement for a realistic system, and also a feature of the accused system. But that is based on our expertise. However, the explanation of the figures in the `105 patent has all the equipment in the provider physician's office [`105: c. 4 l. 4-21].

Hence, the patent must assume full automation at an insurance company, since no terminal facilities are provided there, only an interconnection to their computer systems. The `105 patent is also moot about any processing steps that are performed there, and cites all of the functionality in a single claims element, as in:

> 1(d) means in communication with said input means responsive to **input** of data through said input means symbolic **of symptoms** of one of said predetermined plurality of persons for **tentatively** identifying a proposed mode of **treatment** for said one of said predetermined plurality of persons and, **when** said proposed mode of **treatment includes** one of said **predetermined procedures requiring utilization review**, for producing indicia indicative thereof and **for preventing payment therefor** by said payment means **until** said utilization review has been obtained and **data** indicative **thereof has been entered in** said **system**.

This statement would lead a `person steeped in the art of building computer systems' to consider that all tasks are to be performed within a single system, and not to distribute the tasks among two or more independent entities: the patient's physician and the insurance company. In no way can this claim sentence be expanded to include manual review at the insurance company.

By placing multiple actual process steps into a single claim element the patent de-emphasizes the difficulty of the problem being addressed.

5.5.2. Kaliski must redefine comprehensive.

On pages 10-11, Kaliski, using the statement from the preamble in many of the claims, states that `105 is a `comprehensive system'. But he noted earlier "Nowhere in the specification is **comprehensive** defined to have anything other than its ordinary meaning (see Definition 3.12). However, in reviewing the specification and the claims of the '105 patent, it is clear that the prior art lacked a system possessing the ***"total*** health care function, [`105: c. l. 37] to provide truly **comprehensive** medical care." [`105: c. 1 l. 49] " [Kaliski:2002, p. 8]. Here comprehensiveness in systems claims of `105 and comprehensive medical care are intertwined. The vision of comprehensive health care existed long before the patent was applied for [Kostrzewski:1976] . But a vision, just

like flying to Mars, alone cannot be patented. To deal with the inconsistencies [Kaliski:2002, pp. 9-10] observes:

> However, different levels of **comprehensive**ness and integration are illustrated within the requirements of the different claims themselves.

and that

> It is also apparent that the most complete and fully inclusive apparatus claim of the `105 patent is not described as a "**comprehensive**" system at all; rather, Claim 47, which has *14* different elements reaching as near to the description of the patent specification's preferred embodiment, is described in the preamble as an `***integrated*** health care management system,' harkening back to the description of the preferred embodiment as featuring `the ***integrated*** interconnection and interaction of the patient, health care provider, bank or other financial institution, utilization reviewer/case management and employer so as to include within a single system each of the essential elements to provide patients with complete and comprehensive health care and payment therefor.' [Kaliski:2002, pp. 9-10]*).*

Here the loose integration of such systems becomes clear, while Singer [Singer:2000] insists that it should be a single, i.e., tightly coupled system to qualify for the `105 patent (see Definition 3.22). Footnote 3 expands further on the limited comprehensiveness observed in the actual `105 claims. Having to

> `harken(~~ing~~) back to the description of the preferred embodiment'

to include capabilities not included in the claim is again an unwarranted extrapolation, especially since the specification is an all encompassing vision of health care services, not a description of a built or buildable system.

5.5.3. Kaliski notices that a `smart system' is needed.

Kaliski notices the discontinuity in the `105 claims and the fact that the specification indicates that a `smart system' is needed. He [Kaliki:2002, pp. 4-7] lists instances where the patent requires a `smart system' and concludes that there must be `different kinds of smart systems'. He then uses his expertise to suggest various implementations for such a `smart system'. Again, nowhere in the specifications or in the claims of the patent is the actual implementation of such a `smart system' specified. It cannot have been clear to a person `versed in the art of computing in 1990' how such a smart system might be implemented. The definition partially cited in support of the generality of the term reads in full [Kaliski:2002, exhibits section, page 348 from [Webster's 1988]]:

> **smart**: Having some computational ability of its own. Smart devices usually contain their own microprocessor or microcomputers.

This definition clearly refers to devices, not to entire data processing systems.

Subsequent entries cite "**smart card**", "**smart machines**", and "**smart terminal**" in that sense, but do not include `smart system'. We also noted that later editions [Websters:2000] no longer define "**smart**" as a distinct entry, but still contain the three examples of smart devices. Data processing systems always embody computational abilities, and by Kaliski's generous interpretation all computer systems would be smart systems; we know better.

The patent applicant however uses the attributes associated with being `smart' to differentiate the system proposed in `105 from earlier systems [Cummings II:2000, p. 220 l. 4-15], in the sense of being intelligent. Note that the author of the `105 patent himself (see Section 5.1) describes a smart system as one possessing artificial intelligence (See 3.17).

> means (physician office terminals) as follows: “any of various conventional methods for connecting the input means of claim element l(a) with the data bank memory. Such memory may be part of the terminal that provides the input means (such as physician file Fig. l(44) and discussion at 6:44-54) or part of one or more remote systems to which it may be connected in any of various distributed processing environments (14:53-54), and accessible to it by any number of conventional communication paths (Fig. 1 (1 2)) to the processing system (Fig. 1 (1 0)), which is in turn connected to the database in question (represented by arrows to and from the databases linking Fig. 1 (1 0) to Fig. 1 (1 6-22, and 44)).” Thus, it is my opinion that the nature of the connection includes an input means connected to a processing system where the database in question resides. Regarding whether one of the databases in question includes an identification of predetermined procedures requiring utilization review, I have reviewed and am in agreement with the Expert Report of Dr. Holland, pp. 28-29, that certain of the databases that are used by

Kaliski, by even considering that systems with business rules are smart [Kaliski:2002, p. 7], in effect overturns the arguments made in [Cummings I:2000, p. 162 l. 4-14], that the `105 patent presented an advance in the state-of-the-art by being smart. Systems with business rules had been in use, including in health care reimbursement systems, for many years prior to the application of this patent [Wirtschafter and Mesel, in Alabama].

When referring to Trigon's implementation, however, Kaliski considers the methods being used `algorithms' [Kaliski:2002, p. 50], a term that is used to distinguish common computing methods from smart systems (see Definitions 3.15 and 3.16).

5.5.4. Kaliski does not distinguish Symptoms from Diagnoses.

For the interpretation of these medical terms he relies on Holland, specifically pages 33-44, and 35-40 (at [Kalinski:2002, p.18, and footnote 18 on page 32]. While Kaliski states throughout [Kaliski:2002. pp.18 - twice, 19, 20, 32 -- twice, 34, -- thrice, 35, 36, 38, 39-40, 40 - twice, 50,] that he agrees with [Holland:2002], he cannot do so with authority. [Kalisky:2002, p.87].

Maternity is a condition, and recognizing that condition conveys information [Kaliski:2002, pp. 34-35, p. 38 . Holland:2002 pp. 8-9, pp. 41-42], and shown as an alternative to surgical and medical intervention, and neither a symptom of disease nor a diagnosis. The condition of maternity is misused in [Kaliski:2002: p. 34, p. 38] to explain the possible workings of the `105 patent, variously as an example of a symptom and as an example of a disease.

5.5.5 Only Claims data are available to Trigon.

Kaliski recognizes that the medical history in most claims in `105 (see Definition 3.7) must come from the database, and that the TRIGON database only contains reimbursement claim information, and as such is what we define to be a reimbursement claims history (see Definition 3.8) [Kaliski:2002, p. 47]. Kaliski cites [Holland:2002] in arriving at his definition of a medical history.

5.6 Holland:2002 Report

Stephen Holland is a physician by training and has experience in health care management. Dr. Holland specializes in Long Term Care Underwriting Criteria and Underwriting Processes.

5.6.1 Medical History.

Holland cites Allcare's definition of "Medical History" from the Internet. He also provides the description of medical history from a well recognized textbook -- a `learned treatise' [Noble:2001] [Holland:2002, pp. 29-30]. These two definitions are conceptually similar, and match our simpler definition (see Definition 3.7).

Prior to those citations Holland opines that medical histories are stored in some of the databanks memories at TRIGON, and:

> that each of these databank memories is accessible on the automated health care management system that is used by TRIGON [Holland:2002, p. 22].

This reasoning is continued on page 31, and Holland states that:

> TRIGON has elected in advance to store “predetermined items of medical history,” in a database.

That reasoning may make medical sense, but in practice TRIGON has no control over what items of a medical history it can obtain. TRIGON only receives information relevant to reimbursement and hence can only collect a limited reimbursement claims history (see Definition 3.8). While Holland has found references in TRIGON'S systems that refer to a `Medical History', this is an insurance carrier's misuse of the term, since the items displayed are limited to the reimbursement claims history. If information from a

proper medical history is needed for reimbursement claims adjudication in the TRIMID portion of TRIGON, the medical officer must contact the provider's office by telephone.

TRIGON does archive its reimbursement claim history and keeps it available for subsequent statistical analysis relevant to aggregate cost management. The insurance company's auditors and actuaries are the primary users of the system.

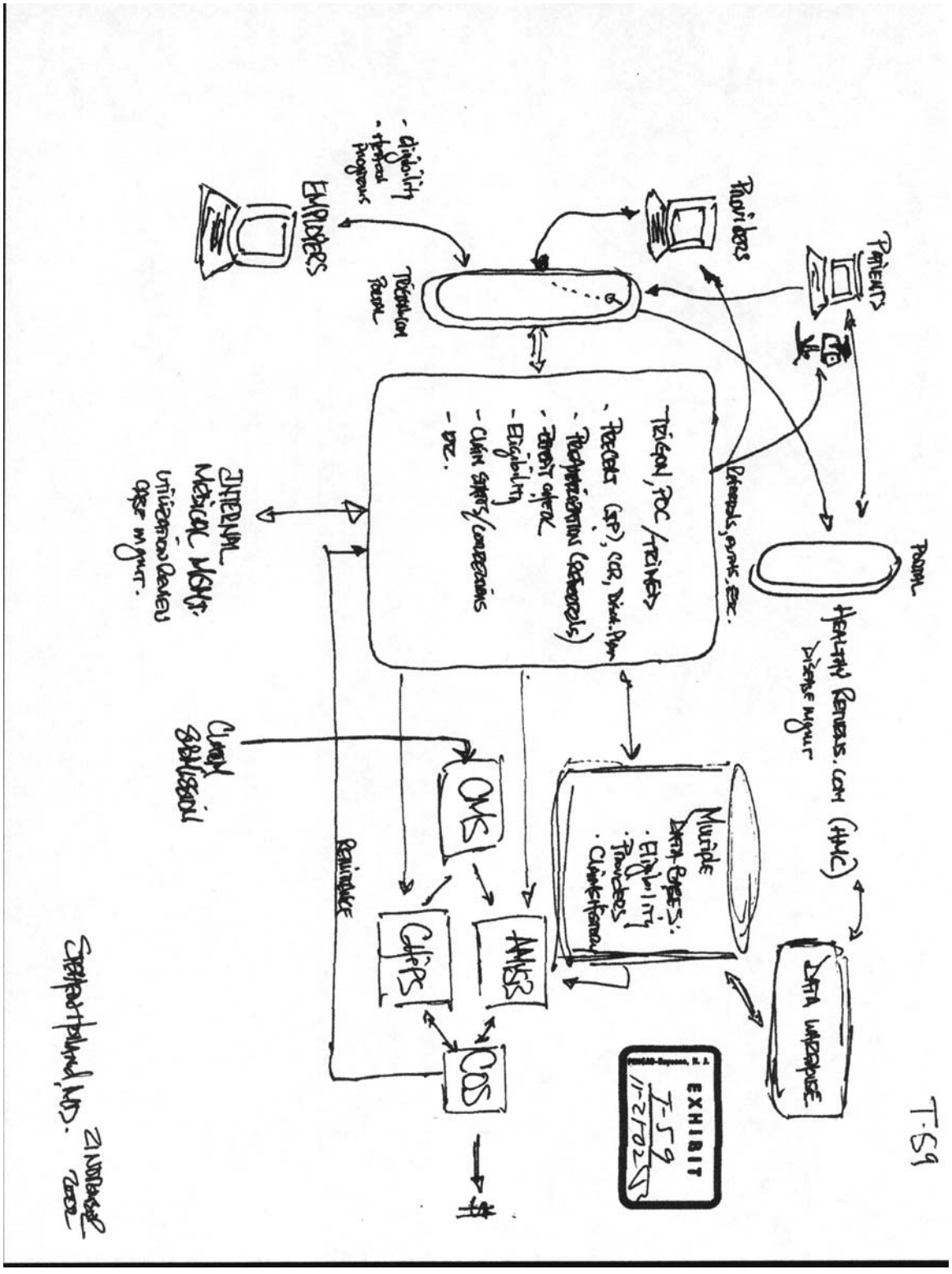
5.6.2 Symptoms are mischaracterized.

While Holland cites a `learned treatise' for Medical History, no equivalent definition is provided for the critical term "Symptom" (see Definition 3.1). Instead Holland uses as examples citations from “The Wisconsin Upper Respiratory Symptom Survey (WURSS)” [Barrett:2002]. This study was unique in that it did not try to determine a diagnosis nor provide treatment. Half of the study subjects had the flu, and the objective of the study was to test what Barrett termed an "illness-specific quality of life instrument." i.e. a measure of discomfort due to flu or the proximity to people having flu symptoms. This study was so unique that it actually found its way into the 11 March 2002 New Yorker Magazine [not cited]. Using this quality-of-life study as a basis for equating symptoms with diagnoses is an imaginative stretch that is inappropriate to costly issues in the practice of health care.

We encoded the terms claimed by [Holland:2002, pp. 37-39] to be symptoms that are used for diagnosis in Appendix 7, and find that all of them require elaboration by a clinician. None of these terms given would be approved for claims reimbursement unless accompanied by a proper diagnosis. There are indeed some symptoms that are pathognomonic and are members of both the symptom and diagnostic class (see Definition 3.1). But no realistic system could restrict itself to such diseases, which likely comprise less than 5% of the healthcare expenditures we incur.

5.7 Holland's 2002 Deposition

In his deposition [Holland:2002D] provides his view of the TRIGON systems [pp. 54-55] as depicted by his sketch.



Holland does not consider himself an expert in reading patents, and focuses on the concepts presented in the specification. He also assumes throughout that the patent is

valid, and uses his health care expertise to mold the vision presented in the `105 patent into structures that are realistic and feasible.

> I understood the concepts pretty easily. The language of the patent is language I'm not familiar with and so it did -- I had to understand how claims were laid out, I had to understand the concepts of background and the embodiment. These are just not concepts I deal with every day, so it was very interesting. [p. 28 Lines 10-17]

Since the specification describes a vision, a vision some medical experts will find very sympathetic, the weaknesses in the patent are minimized. Holland describes the business rules well that precede human adjudication of any claim that might be denied at Trigon (See Section 2.2.2.6 on Trimed).

> Business rules. Those business rules may be related at the highest level, whether this is an eligible patient or not, is the person a member of Trigon Blue Cross/Blue Shield, for instance. The eligibility level it may say, determining whether the insurance is in force at the time the bill was generated, the service was provided. Other business rules may apply, is this a coverage service, so there are business rules that are based on the benefit plan that this eligible member then has purchased and that benefit plan, those business rules, whether perhaps a liposuction is called cosmetic and that procedure and that is not covered, a covered service, those sorts of benefit-based business rules. There will be other business rules on the provider, what is the provider and what fee schedule or what type of payments should they get for the service. If it's a certain type of service such as a referral or in-patient admission, one of those business rules would be to check for pre-authorization or pre-certification, yes or no, is it there and is it a legitimate code perhaps. That is another business rule. Finally, at the end of this adjudicatory process and in each one of those things is the diagnosis correct and acceptable, is it valid, there will be validity edits as well as business rules apply. And if everything is correct and payment can be made, then there'll be further business rules, such as are there any co-pays or deductibles that the patient is responsible for, and at that moment that everything has been applied and everything has gone correctly through -- and I believe that Trigon calls that a clean claim, meaning that all the business rules have been met, that has been automatically adjudicated, it is ready for payment. [p. 62 Lines 1-22, p. 63 Lines 1-21]

But the important aspect, that human medical directors, possibly informed during telephonic conversations with the patient's provider, are required to perform the steps that cannot be automated, is ignored. Moving to the actual patent:

> I described the adjudication that was going on here within the diagram. The '105 patent speaks to adjudication. It teaches to it in Column 13, Lines 31, 32, so Figure 8 is really the, shows in box, I believe, 202 the act of adjudication procedure, that the patent itself speaks of a variety of claims processing systems

> in its background and assumes that there'll be various methods and means of adjudication. In the patent itself in Column 13, Line 32 talks about the adjudication procedures activated as notated on Rectangle 202, so within that there are business rules. It isn't really specific about what those business rules are, but really it was intending to say that they're part of this comprehensive healthcare system, could be a variety of claims payment systems that adjudicative procedures.
>
> Q. And still on Figure 8, is the Box 201 or claim codes accurate part of the adjudicative procedure?
> A. Yes. Those are usually validity checks.
> [p. 66 Lines 2-22, p. 67 Lines 1-3]

Holland's insight of what a comprehensive health care system should contain has expanded the `105 patents visionary elements in Figure 8 with his beliefs and assumptions, rather than restricting them to the claims.

When the patent mentions symptoms, Holland automatically assumes that diagnosis is intended, because that is the only thing that makes sense to him.

> A. The process of utilization review in the patent is shown in Figure 6, Boxes 127, 128 and really is sort of embodied in 5-C of the patent. The data is entered into the system. The system data is symbolic of symptoms and tentatively identified a proposed treatment such as admitting the patient to the hospital for pneumonia. [p. 69 Lines 20-22, p. 70 Lines 1-6].

Pneumonia is clearly a diagnosis, see the second table in Appendix 7.1. Symptoms that the patient presented may have included a cough, coughing up stuff, fever, sweats, chills, plugged ears, or chest congestion, see the first table in Appendix 7.1. It is the physician's role to establish a diagnosis from the presented symptoms and other signs, say the results of a sputum test. Then convert them to a diagnosis. Since the `105 patent proposes `smart' and `expert systems' (see Section 1.1) it also recognized that a process step was required to convert one from the other. Since Holland does not know of any systems that can perform diagnosis automatically, he is forced to continue with that confusion.

> The ICD-9 code becomes the symbolic code of symptoms, maybe cough, fever, hemotatis(sic), which is bleeding from the lung. [p. 70 Lines 6-9]

Cough is a symptom, fever is a sign implicating a host of possible diseases and clearly not a diagnosis that a physician would submit to obtain reimbursement, while Hemostatis is indeed a diagnosis, requiring interaction with the patient to determine the source of the blood produced. Later similar mixed terminology arises at:

> Q. How is the proposed mode of treatment arrived at?
> A. The practice -- the system is designed for a physician to be able to enter that information in. The proposed mode of treatment may be a -- the diagnosis code

> may be angina, which is a symptom, chest pain. The procedure code may be coronary artery bypass graft, which is a proposed treatment. [p.140 Lines 8-17]

and later

> If it's a surgery or upper quadrant pain, a symptom, a procedure called a cystectomy, that procedure will be in the predetermined procedure requiring utilization review which will then pend and produce indicia indicative thereof.
> Q. So the provider must enter data symbolic of the procedure?
> A. Symptoms and procedure, yes. The ICD-9 codes are -- yes.
> [p. 163 Lines 16-22, p. 164 Lines 1-3]

When having to deal directly with the definitions no clarification ensues:

> A. Yes. There would be -- there would be, the vast majority of them would be symptom codes. There could be some purely diagnostic codes that could imply symptoms. Obviously, chronic cholecystitis is a disease but it's also a symptom.

Few patients would so presumptuous to present the term `cholecystitis' as a symptom of their illness to their doctor. See Appendix C if you wish to use it.

> There are symptoms associated with or symbolic of that, of right upper quadrant pain, fever, nausea and vomiting. Internal derangement of the knee is a diagnosis but it has all sorts of symptoms associated with it, swelling, clicking, immobilization, pain.
> Note that none, nor all of those symptoms is adequate for the diagnosis.
> Q. That sounds to me like those symptoms were different than the diagnosis.
> A. No, they are the diagnosis. They are synonymous with the diagnosis even though they're also in and of themselves ICD-9 codes for pain, for vomiting, for effusion, knee effusion.

See Appendix C for encodings of symptoms.

> Q. Well, how do you define a symptom?
> A. A symptom is any state other than normal.

No, that's an illness. See Section 3.1 for the correct definition of symptom.

> Q. And how do you define a sign?
> A. Something I see or feel other than normal.
> Q. That's a medical definition?
> A. Yes. Sign is something that you see or feel.

No, that's a symptom. See Section 3.2 for the correct definition of sign.

> Q. How do you define a diagnosis?
> A. Pathological condition other than normal. I guess that's redundant, pathological condition. Sorry.

[p. 174 Lines 11-22, p. 175 Lines 1-18]

We show definitions and ICD-9 encoding of these terms in Appendices B and C, and note again that the terms used here are a mix of symptoms and diagnosis. None of them are pathognomonic.

In other testimony we find shortcuts.

> If it's a maternity request, request for maternity admission, information is put into the system after the patient is identified and patient admission for maternity is requested. Data symbolic of the patient. [p. 71 Lines 7-12]

An initial report of maternity does not lead to hospital admission, until delivery or if complications arise. The speaker realizes that:

> If it's a normal delivery for maternity, it's going to have an ICD-9 code for labor, a symptom and normal delivery procedure. [p. 163 Lines 13-15]

Maternity is actually not a symptom, sign, nor a disease; it is a condition that does have many medical implications, including provision of supportive medical services. It has been assigned many ICD-9 codes (see the second table in Appendix C). Even here clinical expertise comes into play, to determine date of conception, likelihood of complications due to personal and familial history, and the success of previous births. Approval of specific treatments will require specific diagnosis codes (ICD-9), attached to the maternity condition.

How the `105 process is stated remains unclear in Holland's understanding

> Q: ... data symbolic of patient symptoms for tentatively identifying a proposed mode of treatment when, as I understand your explanation, the entry of the patient's symptoms and the proposed mode of treatment was by the doctor and the entry of the patient's symptoms was not for the purpose of tentatively identifying a proposed mode of treatment
> A. Oh, it absolutely is. The proposed mode of treatment is hospitalization or, as in a referral, it's a referral to another specialist for care. That is what I consider proposed treatment, so it is absolutely proposed treatment. [p. 143 Lines 1-15]

As a physician, Holland just can't see that input of patient symptoms could ever work. Cummings, who is a marketing oriented inventor, having read a bit about expert systems can assign this task as a Miracle to a computer. And a real-estate specialist, helping him define the patent language, Conner, certainly can. But here, Holland's expertise forced him to an extrapolation not warranted by the text of the `105 patent.

> What I'm saying is that the doctors entering some data symbolic of a patient's symptom and as a means leading to a proposed treatment, i.e. hospitalization, surgical procedure, a delivery in the case of maternity or a referral to a specialist in the case of the pre-authorization system, and that proposed treatment is based

on the data symbolic of a patient's symptoms. And that based on that information is what is actually reviewed or criteria are applied to that by the Trigon system automatically and at times will either give an authorization the indicia indicative thereof producing a decision or producing a pend, meaning that it can't be decided and, therefore, has to go off for medical review. If you don't put that data in, it will not do anything, it will not produce a decision.
Q. You don't think that the use of the word "for" implies a cause and effect in that clause?
A. No, no.
Q. Why doesn't the claim just say entering both data symbolic of symptoms and a proposed mode of treatment?
MR. HILL: Objection to the extent it calls for speculation.
A. I didn't write the patent. I don't know. I just think that one leads to -- you know, I might put gas in my car so I can go for this task or that, but whether I do that or not is not a cause and effect. It basically means leading to or corresponding to. That's how I interpret that. [p. 144 Lines 3-22, p.145 Lines 1-16]

Now it becomes obvious that something miraculous is needed:

Isn't it true that the patent describes a smart system which does operate in the cause-and-effect mode as set forth in this limitation 55-D?
A. It does definitely describe the smart system, as a system with criteria rules, but that, I believe, is separate from the statement earlier of what the physician does. The physician is, has certain requirements and has to put in going to the system, select an in-patient admission or in-patient surgical procedure, put in data symbolic of patient's symptoms as a means of identifying a proposed mode of treatment which then goes against the smart system for a cause and effect, you know, that leads to a cause and effect of saying providing authorization or pend. That is how utilization review works. It's criteria-based, putting in information, that information is evaluated and a decision that indicia indicative is provided back to the physician. That is the basis of utilization review. [p. 145 Lines 17-20, p. 146 Lines 1-17]

This is really not pre-certification. This paragraph, to my opinion and my knowledge, does not speak to 52-C but, rather, 64, 65 and 66. This is sort of a diagnosis assistance type system. It's not pre-certification. It's a system that's designed to assist the physician in making a diagnosis and using patterns of treatment protocols, not currently in the pre-certification system of Trigon. [p. 147 Lines 7-16]

Holland now assigns the hard tasks to the provider, not to the accused system at Trigon.

This system is supposed to help the physician, assist the physician in correlating the observed patient's symptoms and test results to help identify the cause, so this really is not being addressed by 52-C. This is really what is described in Claims 64, 65 and 66. It's an assistive device for making of diagnosis and treatment planning. I envision this was envisioned to be some sort of a program that would

help doctors make diagnoses and this is not what 52-C refers to, in my opinion. [p. 147 Lines 17-22, p.148 Lines 1-6]

... most appropriate treatment protocols.
A. This is not pre-certification. It's not referral management. This is something very different. I think it's important that we draw a distinction. This is a diagnosis assistance device. There are programs outside like Ovid and things that physicians use to help them make a diagnosis where you put in symptoms and you're getting back potential diagnoses, and then maybe you should use this drug or that drug or this test or this test. This is not what is envisioned in 55-D. This is really what was envisioned in 64, 65 and 66. [p. 149 Lines 17-22, p. 150 Lines 1-8]

Maybe the mechanism of inputting data is similar between the two, but the outcomes, the output and all the other things inside is not 55-D. I'm passionate about that because this is not pre-certification, which I believe <claim> 55-D speaks to the utilization management. This is diagnosis assistance. This performs doc in a box. [p. 151 Lines 4-11]

The manual steps currently performed in the adjudication process to bridge the gap are again ignored. See Definition 3.18 for the term `doc-in-a-box'.

Holland also employs his expertise in interpreting other portions of the patent:

A. The background Column 1, Line 36, talking about the total healthcare system, they talk about the review of the necessity of implementing selected procedures. They then provide some, including lifestyles, the obtaining of second opinions, utilization review and case management and other functions contemplated by total health management such as ancillary services. So in a sense, the patent is teaching that utilization review is the review of the necessity for implementing selected procedures.
Q. So then, according to this passage, ancillary services is not included in utilization review; is that correct?
A. No. It says "and other functions contemplated." So I took that to mean that that would be part of utilization review because ancillary services are, in large part can be considered procedures or treatments. [p. 73 Lines 2-22, p. 74 Line 1]

and later

Q. But it doesn't say anywhere in here that optional pre-certification is utilization review, correct?
A. No, but in 1990 and today, pre-certification is commonly a component of utilization review.
Q. But that's not set forth here in this patent, correct?
A. I interpret it to be so, but that's my interpretation.
Q. On the basis of the paragraph Column 1, Line 36?
A. Yes.
Q. But that doesn't refer to pre-certifications, does it?

A. What? Excuse me again.
Q. The paragraph that starts on Column 1, Line 36.
A. Yeah, that is, it's the review of the necessity for implementing a selected procedure is pre-certification. That is the definition of pre-certification, is the review of necessity for a procedure. That is commonly held. If you ask somebody what is pre-certification, they're going to say reviewing the necessity of a selected procedure. That procedure could be an admission to the hospital, could be a referral, it could be a referral to a specialist. [p. 75 Lines 4-22, p. 76 Lines 1-11]

Holland's expertise expands on what the patent teaches. It does match what is required in practice and performed at TRIGON. He is well versed on the origins and use of rules that aid a company as TRIGON in approving treatments automatically, and so lessening the load on Trigon' medical experts, and on the providers that must respond to telephone calls from Trigon's medical directors when unresolved reimbursement requests arise.

Holland makes reference to a component system that performs that function, and makes clear the difference between medical utilization review (See Definition 3.9) and the cost-effectiveness review carried out at insurance companies such as Trigon (See Definition 3.10).

Q. So under your definition of "system," was the AMS and the claims processing system together one system?
A. Yes. They were separate entities that came together to produce a system, yes. I wouldn't call it a comprehensive healthcare management system, but I would call it a system, a claims payment system. You could call it a smart claims payment system.
Q. And did that smart claims payment system perform utilization review?
A. It performed a form of utilization review. To a claims manager, what it did, i.e. claim edits that were attempting to look for inappropriate care, inappropriate claims, redundant claims, that is a form of utilization review in a claims environment. But a medical manager, i.e., a physician, a medical director or a nurse working in the medical management department of health care, of a healthcare, health plan, would not consider that utilization review, so you have to understand that terms were used interchangeably and some were embraced by different departments. But utilization review could mean a claims edit. It could mean some of the adjudicatory processes. It would be called a retrospective claim edit because it's a post-claim. There's pre-payment and post-payment, but those were considered in those days a form of utilization review. I don't think today they would be considered that. Moreover, however, that term "utilization review" was quickly applied in 1985 to pre-certification, concurrent review and discharge planning and that started around 1985, although it started in more nascent ways in the Medicare or Medicaid populations a few years before that. But one of the very first utilization review programs was Private Healthcare Systems and that first started in 1985 here in Dedham, Massachusetts, and they would say the pre-certification and definitely pre-certification, concurrent review and discharge planning were all part of utilization review. [p. 101 Lines 21-22, p. 102 Lines 1-22, p. 103 Lines 1-22, p. 104 Lines 1-2]

Holland' had expressed his views. He was associated with OptiMed. But all of this information goes way beyond what the patent teaches.

The components were prior art, and the question now arises if the `105 patent requires their tight integration (see Definition. 3.22 for integration) or a looser distribution.

If the requirement of `105 is a single, tightly coupled system

> include within a single system each of the essential participants to provide patients with complete and comprehensive pre-treatment, treatment and post-treatment health care and predetermined financial support therefor. [`105: abstract]

then the prior art cited by Holland is indeed a mere subset. This interpretation makes TRIGON, not being tightly integrated, but having many components, some operated by other organizations according to their rules, (for example the accused subsystems Bon Secours Health Systems, Columbia/HCA, and Provider-based Practice Management Systems) not a system that infringes.

If the `105 patent is not that strictly interpreted, considering statements as:

> It is still another object of the invention to provide an integrated health care management system including interactive participation with patients' employers and banks. [`105: c. 2 l. 11-14]

or following Kaliski's [Kaliski:2002] reasoning (See Section 5.5), then a wide collection of actually integrated and integratable prior art should be included. If the patent would still be valid, then TRIGON as of today might be an infringer, but TRIGON's predecessors might be valid prior art. This argument excludes the execution of the miracle (see Section 1.1), which Holland cannot perceive, because he is steeped in actual, realized, and operating components of Health care reimbursement systems
.
Those systems, at the time relied also on manual communications:

> [p. 105 Lines 1-22, p. 106 Lines 1-2]
> planning module. In 1993 or '94, a referral management module was added to the system.
> Q. But the other components were present in 1990?
> A. Yes. They were actually present in 1985, '86.
> Q. When you say --
> A. It was a product owned by the Health Data Institute and in 1990 the Health Data Institute was broken up and sold by the parent company, Baxter, and myself and two friends bought the Optimed Medical Systems.
> Q. And you say it was a phone-based system?

A. Yes. It was made for nurses that sat at a terminal and read questions off the screen and doctors would call in and they would talk to the doctor and their staff, answer questions and then would produce a decision to pre-authorize, assign a length of stay.
Q. What was the typical response time for that type of thing to happen?
A. Typical phone call?
Q. Yes.
A. It was five to 12 minutes.

In summary, Holland is an expert trying to make sense of the patent, often by glossing over issues that would be problems for someone who has to rely on the patent to understand what is intended. We cite an example of the attitude:

[p. 209 Lines 10-19]
A. In this, I believe -- excuse me. In my opinion, preventing payment therefore is based on the fact that something required utilization review, produced an indicia indicative thereof, meaning a pend status until said utilization review has been obtained, and data indicative thereof has been entered into the system, thereby allowing payment to go through. That's the way I read it. How else could you read it?

We learn much from this deposition. When the expert becomes merely confused, we find serious problems. Maybe we could repair the `105 patent problems as well, but that is not our task here.

5.8 Expert Reports by Kurtyka,

5.8.1 Bank One System [Kurtyka:2000].

Gerald Kurtyka provided an extensive description of the background and functionality of the Bank One system (occasionally cited as the Banc One System), early interactions with allcare principals, and the actual implementation of some of the envisaged functionality at a site in Wisconsin [Kurtyka:2000]. He entered the field from a banking background, so that payment management aspects of the system developed at Bank One under his guidance are particularly strong. Health care input was mainly through relevant banking customer interaction, including large employers with concerns about managing their growing healthcare expenses. The concepts were developed in the 1988-1989 period. Technical support was provided by a Services Corporation, associated with Bank One, including a Mr. Lyons, who participated in some of the subsequent meetings. The documentation, generated in 1989, presages all of the claimed functionality of the `105 patent, with the exception for course of expert systems capability and entry of Symptoms [BankOne:1989]. The bank functions as a central clearing house, and electronic linkages are to be provided to providers and hospitals, insurance companies, employers, and patients for copayments. In the Bank One systems Diagnosis codes (ICD) are to be entered by the providers, as well as treatment codes (CPT) and eventually drug codes for prescriptions.
Utilization review is to be performed by the insurance companies or equivalent payers.

The Bank One system was shown to Cummings at an AHA meeting in May 1990, where

> "Mr. Cummings was very excited and stated "I've been working on exactly the same thing!".

Kurtyka met Cummings and Conner subsequently a number of times. Kurtyka discussed implementation at Florida Hospital where Mr Cummings was employed hoping for an implemetation there of the Bank One system. Kurtyka visited Cummings at Florida Hospital on several occasions. Mr. Cummings always represented himself as an employee of Florida Hospital and to be acting in his capacity as an officer of Florida Hospital. Kurtya was puzzled by Conner's role and Conner's request to sign a non-disclosure agreement with Allcare. Since the Bank One documents we have seen preceded those meetings there was no information flow from Allcare to Bank One.

Kurtyka publicized and shared the information about Bank One's Medical Payment System freely at meetings in his quest to find customers for AllCare..

5.8.2 Kurtyka 2002 Deposition [Kurtyka:2002]

A second deposition, in November 2002, largely validated the earlier deposition, although Kurtyka here stated that Cummings' vision largely overlapped the Bank One approach, but included additional medical capabilities. Kurtyka considers the specifications as part of the patent, even when not substantiated by any of the claims (p.176, 177). For instance, the Bank One system itself does not do adjudication, while the `105 system specifies that function. However, when `seen from the 50 000 foot level' the systems that include Bank One as front end does match the `105 patent. Kurtyka clearly

understands that financial responsibilities in health care financing are and should be partitioned over distinct organizations.

When reviewing Trigon he opines clearly that Trigon is a payment system, and not a comprehensive health care systems as defined in the `105 patent specification.

5.8.3 **Trigon System Architecture.**

Figure 1 of [Kurtyka:2002] (presented in Section 2.1 of this report) summarizes the TRIGON system. The label of this figure is "Trigon Medical Payments System". It is interesting that the figure omits showing terminals for the Medical Directors of TRIMED, the TRIGON module for reimbursement claim payment adjudication. It appear that since the `105 patent omitted such terminals, it was convenient to forget about their existence in TRIGON.

5.9 Barber et al., patent 4858121 August, 1989.

This `121 patent shows a great deal of overlap with the Allcare patent. Some initial figures are nearly identical. It appears to represent an actual implemented system, by the Assignee, MPS. The intent of this patent seems indeed to protect existing intellectual property.

The `121 system is a payment system, focusing on patient insurance and treatment information. It does not require entry of symptoms for automation of the claims process. When required for a claim, the diagnostic codes and treatment codes are entered. The system collects the information and verifies eligibility. It does not carry out utilization review nor cost-effectiveness reviews, but forwards verified information to the actual insurance carriers for further processing.

The patent is well described, and a person conversant with state of the art in communicating financial systems would be able to create functional systems from the specification.

The operations described in `121 are quite similar to the operations of the front-end of the TRIGON system.

The patent distinguishes itself from the `105 patent by its intent, realism, and specificness.

5.10 Watanabe, patent 4797543 January, 1989.

The `543 patent describes a 'smart card' containing a processor and memory. It is an important aspect of some claims of the Cummings `105 patent system, but not of any that Allcare is asserting versus TRIGON. It is also relevant to the Barber `121 patent.

5.11 Pritchard, patent 4491725 January, 1985.

The `725 patent teaches the use of a 'smart card', as invented in `543, to verify medical insurance eligibility. It is conceptually a subset of the Barber `121 patent. It is not relevant to this case since Allcare is not asserting any claims involving smart cards versus TRIGON. It is significant only to the extent that this technology was incorporated in the Bank-One System (see 4.5.1), and the related argument by [Singer:2000, p.12] (see Section 5.3).

5.12 Valentino, patent 4648037 March, 1987.

The `037 patent describes remote access for employees to their insurance and other information. It focuses on the operation of central terminals, kept available to all employees for that purpose. The security code - password - is the employees Social Security Number! The patent predates the ubiquity of terminals. It is not very relevant to the modern world or to the `105 patent.

5.13 Doyle, Jr. et al., patent 4916611 April 1990.

The `611 patent expands on Pritchard's `725 patent by including more up-to-date records and including the coverage rules of the CORBA legislation. Since it also relies on a card for patient identification it is not relevant to this case since Allcare is not asserting any claims involving smart cards versus TRIGON.

5.14 Deschenes et al., patent 3697693 October, 1972.

The `693 patent describes a mechanical terminal for reading credit card and amount-to-be charged information, as well as a system which receives that information in real time and provides an authorized or reject response. It is not relevant to the `105 patent or the TRIGON systems.

5.15 Mohlenbrock et al., patent 5018067 May, 1991.

The `067 patent teaches the use of diagnostic codes (ICD), combined with some patient information as sex and age, in order to predict items of concern in costing of medical care, as length of stay in a hospital and other resources. It warns providers when resource use exceeds or fails to meet expectation significantly, in that sense providing some utilization review.

The prediction is based on an extensive analysis over many pages. It factors in the problem of having multiple diagnoses for a patient by simply counting them, and admits

it cannot provide as good a prediction when the situations gets that complex. To maximize benefits to a hospital, it groups diagnoses into the diagnostic DRG groups that are used for government-supported reimbursement.

Of note to the `105 patent are:

1. No 'smart system' is used, but rather statistics, and the limitation of statistical based prediction is well understood.
2. The starting point is diagnoses, not symptoms as in `105.
3. There is no attempt to predict required treatments, only aggregate factors as length of stay and total resource consumption.

If a `105 system would ever be implemented some of its features would likely be modified, as implied by [Holland:2002] and [Kalinski:2002]. In that case, such an implementation might infringe on this `067 patent.

5.16 Sinay 4290114 September, 1981.

The `114 patent teaches how to use symptoms and signs encountered by a paramedic in order to provide a list of appropriate treatments and a diagnoses. A simple look-up program is described. I believe that this patent is naïve and would not be used in practice. Its use could create grave risks to patients, even though the setting where it is deemed applicable is when no qualified physicians are available. A demonstration of a table lookup for a few simple cases is not adequate to prove its generality. Note that I could not access the images.

The patent does define diagnosis in a responsible manner: As used below, diagnosis means the determination of the patient's malady based on an evaluation of a set of symptoms and findings.

The proposed setting differs from the one contemplated in the `105 patent and the actual one at TRIGON. If a system as this would have reached operational state, it could be an argument that the methods needed for the `105 patent are feasible. It could also have saved much money for the U.S. government, which has, and continues to, spend many millions in improving the diagnostic processes in medicine.

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Appendices

There are currently 4 appendices:

A. My vitae and a reduced biography (submitted separately)
B. Symptoms Misused as Diagnoses in Plaintiff Testimony
C. Definitions of Medical Terms used in the report and in relevant testimonies
D. Claims clusters to structure the `105 patent

Appendix A. Gio Wiederhold's CV (attached)

Appendix B. Symptoms Misused as Diagnoses in Plaintiff Testimony

In this appendix we list 32 terms cited by [Holland:2002] in his argument that equates symptoms to diagnoses. Only Diagnoses, encoded by an ICD-9-CM code are admissible in the TRIGON system for reimbursement, while the `105 patent is based on entry of symptoms. ICD-9-CM is the most current version of ICD-9 and includes many additions since ICD-9 was introduced about 20 years earlier. We hence list for each of those 32 terms the ICD-9 code or "none", as determined by a professional coder, Pat Russo, for reimbursement health claim using a program called the AutoCoder. As she expresses her doubts about the ability of ICD9 to encode these terms, she says :

> " ... I am not confident the AutoCoder output is what the requestor is seeking. Autocoder is little more that a data base of codes and their descriptions. The codes it houses are ICD (International Classification of Diseases) codes, CPT (Current Procedural Terminology) codes, and HCPCS (Health Care Finance Administration Common Procedure Coding System) codes. A user can enter a code and get the text description or enter a word or phrase and get in return a list of codes, which contain or are related to the word or phrase entered. It is not an intelligent system. In other words, it cannot take two or more diagnoses or procedures and determine primary, secondary diagnosis or determine how the case should be coded."

Only 12 of the 32 symptoms have a representative encoding. Observe that none of these encoded Symptoms are adequate to determine treatment, changes in lifestyle, or ancillary services, the objectives of the claims in `105. In summary:

- The symptom "COUGH INTERFERING WITH SLEEP" had no encoding.
- The symptom "PLUGGED NOSE" had no encoding.
- The symptom "FEELING “RUN DOWN”" had no encoding
- The symptom "PLUGGED EARS" identified a procedure code.
- The symptom "RUNNY NOSE" had no unique encoding. (6 candidates)
- The symptom "RUNNY NOSE" closest ICD-9 match was chronic sinusitis. (not chronic)
- The symptom "SINUS PRESSURE" was encoded as "RUNNY NOSE". (not identical)
- The symptom "SINUS PAIN" was encoded as "Other diseases of nasal cavity and sinuses " (not a disease)
- The symptom "COUGH" was encoded as "other chest symptoms" and excluded several different kinds of cough.
- The symptom "COUGHING UP STUFF" was encoded as "COUGH" (not identical)
- The symptom "SORE THROAT" was encoded as acute or viral. (not the same)
- The symptom "SCRATCHY THROAT" was encoded as "SORE THROAT" (not identical)

- The symptom "HOARSENESS" was encoded as "Other Symptoms involving head and neck" (too vague)
- The symptom "STUFFY NOSE" was encoded as "Other diseases of nasal cavity and sinuses" (not a disease)
- The symptom "SNEEZING" was encoded as 784.9 other symptoms involving head and neck including Choking sensation, Halitosis, and Mouth breathing. (not the same)
- The symptom "LOSS OF APPETITE" was encoded as anorexia. (not the same)
- The symptom "IRRITABILITY" was encoded as other ill-defined and unknown causes of morbidity and mortality including Nervousness. (not the same)
- The symptom "EAR DISCOMFORT" did not have a unique encoding. (3 candidates)
- The symptom "WATERY EYES " was encoded as "Other disorders of lacrimal system" (too vague)
- The symptom "HEAD CONGESTION" was encoded as "SNEEZING". (not the same)
- The remaining 12 symptoms of LACK OF ENERGY, HEADACHE, FEVER, SWEATS, MUSCLE ACHES, CHILLS, FEELING DIZZY, FEELING TIRED, SWOLLEN GLANDS, EYE DISCOMFORT, CHEST CONGESTION, and HEAVINESS IN CHEST have representative encoding.

Holland also cited MATERNITY. It does have an ICD-9 encoding, however, since it is considered a condition, rather than a symptom or a diagnosis, specific further information has to be provided to identify reimbursable events, as shown on the table below.

This table was generated from information at The Philadelphia Medical Mall http://www.tpmm.com/services/ICD9/1TABULAR.HTM and from the AutoCoder.

Symptom	**suggested encoding followed by full text description**
COUGH	786.2 786 Symptoms involving respiratory system and other chest symptoms 786.2 Cough Excludes: cough: psychogenic (306.1) smokers' (491.0) with hemorrhage (786.3)
COUGHING UP STUFF	786.2 786 Symptoms involving respiratory system and other chest symptoms 786.2 Cough Excludes: cough: psychogenic (306.1) smokers' (491.0) with hemorrhage (786.3)
COUGH INTERFERING WITH SLEEP	TERM NOT RECOGNIZED
SORE THROAT	462 462 Acute pharyngitis

	Acute sore throat NOS Pharyngitis (acute): NOS gangrenous infective phlegmonous pneumococcal staphylococcal suppurative ulcerative Sore throat (viral) NOS Viral pharyngitis Excludes: abscess: peritonsillar [quinsy] (475) pharyngeal NOS (478.29) retropharyngeal (478.24) chronic pharyngitis (472.1) infectious mononucleosis (075) that specified as (due to): Coxsackie (virus) (074.0) gonococcus (098.6) herpes simplex (054.79) influenza (487.1) septic (034.0) streptococcal (034.0)
SCRATCHY THROAT	462 462 Acute pharyngitis Acute sore throat NOS Pharyngitis (acute): NOS gangrenous infective phlegmonous pneumococcal staphylococcal suppurative ulcerative Sore throat (viral) NOS Viral pharyngitis Excludes: abscess: peritonsillar [quinsy] (475) pharyngeal NOS (478.29) retropharyngeal (478.24) chronic pharyngitis (472.1) infectious mononucleosis (075) that specified as (due to): Coxsackie (virus) (074.0) gonococcus (098.6) herpes simplex (054.79) influenza (487.1) septic (034.0)

	streptococcal (034.0)
HOARSENESS	784.49 784 Symptoms involving head and neck 784.4 Voice disturbance 784.49 Other Change in voice Dysphonia Hoarseness Hypernasality Hyponasality
RUNNY NOSE (473 = Chronic sinusitis)	1. UNSPECIFIED SINUSITIS (CHRONIC) 2. CHRONIC MAXILLARY SINUSITIS 3. CHRONIC FRONTAL SINUSITIS 4. CHRONIC ETHMOIDAL SINUSITIS 5. CHRONIC SPHENOIDAL SINUSITIS 6. OTHER CHRONIC SINUSITIS "ENTER A NUMBER FOR YOUR SELECTION" 1. 473.9 2. 473.0 3. 473.1 4. 473.2 5. 473.3 6. 473.8
PLUGGED NOSE	TERM NOT RECOGNIZED
STUFFY NOSE	478.1 478 Other diseases of upper respiratory tract 478.0 Hypertrophy of nasal turbinates 478.1 Other diseases of nasal cavity and sinuses Abscess of nose (septum) Necrosis of nose (septum) Ulcer of nose (septum) Cyst or mucocele of sinus (nasal) Rhinolith Excludes: varicose ulcer of nasal septum (456.8)
SNEEZING	784.9 784.9 Other symptoms involving head and neck Choking sensation Halitosis Mouth breathing
HEADACHE	784.0 784.0 Headache Facial pain Pain in head NOS Excludes: atypical face pain (350.2) migraine (346.0-346.9) tension headache (307.81)
FEVER	780.6 780 General symptoms 780.6 Fever

	Chills with fever Fever NOS Hyperpyrexia NOS Pyrexia NOS Pyrexia of unknown origin Excludes: pyrexia of unknown origin (during): in newborn (778.4) labor (659.2) the puerperium (672)
SWEATS	780.8 780.8 Hyperhidrosis Diaphoresis Excessive sweating
MUSCLE ACHES	729.1 729 Other disorders of soft tissues 729.1 Mylagia and myositis, unspecified Fibromyositis NOS
FEELING “RUN DOWN”	TERM NOT RECOGNIZED
LOSS OF APPETITE	783.0 783 Symptoms concerning nutrition, metabolism, and development 783.0 Anorexia Loss of appetite Excludes: anorexia nervosa (307.1) loss of appetite of nonorganic origin (307.59)
CHILLS	780.9 780.9 Other general symptoms Amnesia (retrograde) Chill(s) NOS Generalized pain Hypothermia, not associated with low environmental temperature Excludes: hypothermia: NOS (accidental) (991.6) due to anesthesia (995.89) of newborn (778.2-778.3) memory disturbance as part of a pattern of mental disorder
FEELING DIZZY	780.4 780.4 Dizziness and giddiness Light-headedness Vertigo NOS Excludes: Ménière's disease and other specified vertiginous syndromes (386.0-386.9)
FEELING TIRED	780.79 780 General symptoms 780.7 Malaise and fatigue Asthenia NOS Lethargy Postviral (asthenic) syndrome Tiredness Excludes: debility, unspecified (799.3) fatigue (during):

	combat (308.0-308.9) heat (992.6) pregnancy (646.8) neurasthenia (300.5) senile asthenia (797)
IRRITABILITY	799.2 799 Other ill-defined and unknown causes of morbidity and mortality 799.2 Nervousness "Nerves"
SINUS PAIN	478.1 478 Other diseases of upper respiratory tract 478.0 Hypertrophy of nasal turbinates 478.1 Other diseases of nasal cavity and sinuses Abscess of nose (septum) Necrosis of nose (septum) Ulcer of nose (septum) Cyst or mucocele of sinus (nasal) Rhinolith Excludes: varicose ulcer of nasal septum (456.8)
SINUS PRESSURE	GIVES SAME LISTING AS “RUNNY NOSE”
SWOLLEN GLANDS	785.6 785 Symptoms involving cardiovascular system 785.6 Enlargement of lymph nodes Lymphadenopathy "Swollen glands" Excludes: lymphadenitis (chronic) (289.1-289.3) acute (683)
PLUGGED EARS	TERM IDENTIFIES A PROCEDURE
EAR DISCOMFORT	1. OTALGIA, UNSPECIFIED 2. OTOGENIC PAIN 3. REFERRED OTOGENIC PAIN “ENTER A NUMBER FOR YOUR SELECTION.” 1. 388.70 2. 388.71 3. 388.72
WATERY EYES	375.89 375 Disorders of lacrimal system 375.8 Other disorders of lacrimal system 375.81 Granuloma of lacrimal passages 375.89 Other
EYE DISCOMFORT	379.91 379 Other disorders of eye 379.9 Unspecified disorder of eye and adnexa 379.91 Pain in or around eye
HEAD CONGESTION	784.9 784.9 Other symptoms involving head and neck Choking sensation Halitosis Mouth breathing

CHEST CONGESTION	514 514 Pulmonary congestion and hypostasis Hypostatic: bronchopneumonia pneumonia Passive pneumonia Pulmonary congestion (chronic) (passive) Pulmonary edema: NOS chronic Excludes: acute pulmonary edema: NOS (518.4) with mention of heart disease or failure (428.1)
HEAVINESS IN CHEST	786.59 786 Symptoms involving respiratory system and other chest symptoms 786.5 Chest pain 786.59 Other Discomfort in chest Pressure in chest Tightness in chest Excludes: pain in breast (611.71)
LACK OF ENERGY	780.79 780.79 780 General symptoms 780.7 Malaise and fatigue Asthenia NOS Lethargy Postviral (asthenic) syndrome Tiredness Excludes: debility, unspecified (799.3) fatigue (during): combat (308.0-308.9) heat (992.6)

In the Holland deposition [Holland:2002D] several more terms, either symptoms or diagnosis, were mentioned. Here is their ICD-9-CM encoding.

Term	**ICD-9-CM Encoding**
PNEUMONIA	480 Viral pneumonia 480.0 Pneumonia due to adenovirus 480.1 Pneumonia due to respiratory syncytial virus 480.2 Pneumonia due to parainfluenza virus 480.8 Pneumonia due to other virus not elsewhere classified Excludes: congenital rubella pneumonitis (771.0) influenza with pneumonia, any form (487.0) pneumonia complicating viral diseases classified elsewhere (484.1-484.8) 480.9 Viral pneumonia, unspecified 481 Pneumococcal pneumonia [Streptococcus pneumoniae pneumonia] Lobar pneumonia, organism unspecified

	482 Other bacterial pneumonia 482.0 Pneumonia due to Klebsiella pneumoniae 482.1 Pneumonia due to Pseudomonas 482.2 Pneumonia due to Hemophilus influenzae [H. influenzae] 482.3 Pneumonia due to Streptococcus Excludes: Streptococcus pneumoniae pneumonia (481) 482.30 Streptococcus, unspecified 482.31 Group A 482.32 Group B 482.39 Other Streptococcus 482.4 Pneumonia due to Staphylococcus 482.8 Pneumonia due to other specified bacteria Excludes: pneumonia complicating infectious disease classified elsewhere (484.1-484.8) 482.81 Anaerobes Gram-negative anaerobes Bacteroides (melaninogenicus) 482.82 Escherichia coli [E. coli] 482.83 Other gram-negative bacteria Gram-negative pneumonia NOS Proteus Serratia marcescens Excludes: gram-negative anaerobes (482.81) 482.89 Other specified bacteria 482.9 Bacterial pneumonia unspecified 483 Pneumonia due to other specified organism 483.0 Mycoplasma pneumoniae Eaton's agent Pleuropneumonia-like organisms [PPLO] 483.8 Other specified organism 484 Pneumonia in infectious diseases classified elsewhere Excludes: influenza with pneumonia, any form (487.0) 484.1 Pneumonia in cytomegalic inclusion disease Code first underlying disease, as: (078.5) 484.3 Pneumonia in whooping cough Code first underlying disease, as: (033.0-033.9) 484.5 Pneumonia in anthrax Code first underlying disease (022.1) 484.6 Pneumonia in aspergillosis Code first underlying disease (117.3) 484.7 Pneumonia in other systemic mycoses Code first underlying disease Excludes: pneumonia in: candidiasis (112.4) coccidioidomycosis (114.0) histoplasmosis (115.0-115.9 with fifth-digit 5) 484.8 Pneumonia in other infectious diseases classified elsewhere Code first underlying disease, as: Q fever (083.0) typhoid fever (002.0) Excludes: pneumonia in:

	actinomycosis (039.1) measles (055.1) nocardiosis (039.1) ornithosis (073.0) Pneumocystis carinii (136.3) salmonellosis (003.22) toxoplasmosis (130.4) tuberculosis (011.6) tularemia (021.2) varicella (052.1) 485 Bronchopneumonia, organism unspecified Bronchopneumonia: hemorrhagic terminal Pleurobronchopneumonia Pneumonia: lobular segmental Excludes: bronchiolitis (acute) (466.1) chronic (491.8) lipoid pneumonia (507.1) 486 Pneumonia, organism unspecified Excludes: hypostatic or passive pneumonia (514) influenza with pneumonia, any form (487.0) inhalation or aspiration pneumonia due to foreign materials (507.0-507.8) pneumonitis due to fumes and vapors (506.0) 487 Influenza Excludes: Hemophilus influenzae [H. influenzae]: infection NOS (041.5) laryngitis (464.0) meningitis (320.0) pneumonia (482.2) 487.0 With pneumonia Influenza with pneumonia, any form Influenzal: bronchopneumonia pneumonia 487.1 With other respiratory manifestations Influenza NOS Influenzal: laryngitis pharyngitis respiratory infection (upper) (acute) 487.8 With other manifestations Encephalopathy due to influenza Influenza with involvement of gastrointestinal tract Excludes: "intestinal flu" [viral gastroenteritis] (008.8)
MATERNITY	NORMAL DELIVERY, AND OTHER INDICATIONS FOR CARE IN PREGNANCY, LABOR, AND DELIVERY (650-659) The following fifth-digit subclassification is for use with categories 651-659 to denote the current episode of care:

	0 unspecified as to episode of care or not applicable 1 delivered, with or without mention of antepartum condition 2 delivered, with mention of postpartum complication 3 antepartum condition or complication 4 postpartum condition or complication 650 Normal delivery Delivery requiring minimal or no assistance, with or without episiotomy, without fetal manipulation [e.g., rotation version] or instrumentation [forceps] of a spontaneous, cephalic, vaginal, full-term, single, live-born infant. This code is for use as a single diagnosis code and is not to be used with any other code in the range 630-676. Use additional code to indicate outcome of delivery (V27.0) Excludes: breech delivery (assisted) (spontaneous) NOS (652.2) delivery by vacuum extractor, forceps, cesarean section, or breech extraction, without specified complication (669.5-669.7) 651 Multiple gestation Requires fifth digit; valid digits are in [brackets] under each code. See beginning of section 650-659 for definitions. 651.0 Twin pregnancy [0,1,3] 651.1 Triplet pregnancy [0,1,3] 651.2 Quadruplet pregnancy [0,1,3] 651.3 Twin pregnancy with fetal loss and retention of one fetus [0,1,3] 651.4 Triplet pregnancy with fetal loss and retention of one or more fetus(es) [0,1,3] 651.5 Quadruplet pregnancy with fetal loss and retention of one or more fetus(es) [0,1,3] 651.6 Other multiple pregnancy with fetal loss and retention of one or more fetus(es) [0,1,3] 651.8 Other specified multiple gestation [0,1,3] 651.9 Unspecified multiple gestation [0,1,3] 652 Malposition and malpresentation of fetus Requires fifth digit; valid digits are in [brackets] under each code. See beginning of section 650-659 for definitions. Code first any associated obstructed labor (660.0) 652.0 Unstable lie [0,1,3] 652.1 Breech or other malpresentation successfully converted to cephalic presentation [0,1,3] Cephalic version NOS 652.2 Breech presentation without mention of version [0,1,3] Breech delivery (assisted) (spontaneous) NOS 652.3 Transverse or oblique presentation

	[0,1,3] Oblique lie Transverse lie Excludes: transverse arrest of fetal head (660.3) 652.4 Face or brow presentation [0,1,3] Mentum presentation 652.5 High head at term [0,1,3] Failure of head to enter pelvic brim 652.6 Multiple gestation with malpresentation of one fetus or more [0,1,3] 652.7 Prolapsed arm [0,1,3] 652.8 Other specified malposition or malpresentation [0,1,3] Compound presentation 652.9 Unspecified malposition or malpresentation [0,1,3] 653 Disproportion Requires fifth digit; valid digits are in [brackets] under each code. See beginning of section 650-659 for definitions. Code first any associated obstructed labor (660.1) 653.0 Major abnormality of bony pelvis, not further specified [0,1,3] Pelvic deformity NOS 653.1 Generally contracted pelvis [0,1,3] Contracted pelvis NOS 653.2 Inlet contraction of pelvis [0,1,3] Inlet contraction (pelvis) 653.3 Outlet contraction of pelvis [0,1,3] Outlet contraction (pelvis) 653.4 Fetopelvic disproportion [0,1,3] Cephalopelvic disproportion NOS Disproportion of mixed maternal and fetal origin, with normally formed fetus 653.5 Unusually large fetus causing disproportion [0,1,3] Disproportion of fetal origin with normally formed fetus Fetal disproportion NOS Excludes: that when the reason for medical care was concern for the fetus (656.6) 653.6 Hydrocephalic fetus causing disproportion [0,1,3] Excludes: that when the reason for medical care was concern for the fetus (655.0) 653.7 Other fetal abnormality causing disproportion [0,1,3] Conjoined twins Fetal: ascites hydrops myelomeningocele sacral teratoma tumor 653.8 Disproportion of other origin [0,1,3] Excludes: shoulder (girdle) dystocia (660.4)

	653.9 Unspecified disproportion [0,1,3] 654 Abnormality of organs and soft tissues of pelvis Requires fifth digit; valid digits are in [brackets] under each code. See beginning of section 650-659 for definitions. Includes: the listed conditions during pregnancy, childbirth, or the puerperium Code first any associated obstructed labor (660.2) 654.0 Congenital abnormalities of uterus [0-4] Double uterus Uterus bicornis 654.1 Tumors of body of uterus [0-4] Uterine fibroids 654.2 Previous cesarean delivery [0,1,3] Uterine scar from previous cesarean delivery 654.3 Retroverted and incarcerated gravid uterus [0-4] 654.4 Other abnormalities in shape or position of gravid uterus and of neighboring structures [0-4] Cystocele Pelvic floor repair Pendulous abdomen Prolapse of gravid uterus Rectocele Rigid pelvic floor 654.5 Cervical incompetence [0-4] Presence of Shirodkar suture with or without mention of cervical incompetence 654.6 Other congenital or acquired abnormality of cervix [0-4] Cicatricial cervix Polyp of cervix Previous surgery to cervix Rigid cervix (uteri) Stenosis or stricture of cervix Tumor of cervix 654.7 Congenital or acquired abnormality of vagina [0-4] Previous surgery to vagina Septate vagina Stenosis of vagina (acquired) (congenital) Sricture of vagina Tumor of vagina 654.8 Congenital or acquired abnormality of vulva [0-4] Fibrosis of perineum Persistent hymen Previous surgery to perineum or vulva Rigid perineum Tumor of vulva Excludes: varicose veins of vulva (671.1) 654.9 Other and unspecified [0-4] Uterine scar NEC

	655 Known or suspected fetal abnormality affecting management of mother Requires fifth digit; valid digits are in [brackets] under each code. See beginning of section 650-659 for definitions. Includes: the listed conditions in the fetus as a reason for observation or obstetrical care of the mother, or for termination of pregnancy 655.0 Central nervous system malformation in fetus [0,1,3] Fetal or suspected fetal: anencephaly hydrocephalus spina bifida (with myelomeningocele) 655.1 Chromosomal abnormality in fetus [0,1,3] 655.2 Hereditary disease in family possibly affecting fetus [0,1,3] 655.3 Suspected damage to fetus from viral disease in the mother [0,1,3] Suspected damage to fetus from maternal rubella 655.4 Suspected damage to fetus from other disease in the mother [0,1,3] Suspected damage to fetus from maternal: alcohol addiction listeriosis toxoplasmosis 655.5 Suspected damage to fetus from drugs [0,1,3] Excludes: fetal distress in labor and delivery due to drug administration (656.3) 655.6 Suspected damage to fetus from radiation [0,1,3] 655.8 Other known or suspected fetal abnormality, not elsewhere classified [0,1,3] Suspected damage to fetus from: environmental toxins intrauterine contraceptive device 655.9 Unspecified [0,1,3] 656 Other fetal and placental problems affecting management of mother Requires fifth digit; valid digits are in [brackets] under each code. See beginning of section 650-659 for definitions. 656.0 Fetal-maternal hemorrhage [0,1,3] Leakage (microscopic) of fetal blood into maternal circulation 656.1 Rhesus isoimmunization [0,1,3] Anti-D [Rh] antibodies Rh incompatibility 656.2 Isoimmunization from other and unspecified blood-group incompatibility [0,1,3] ABO isoimmunization 656.3 Fetal distress [0,1,3] Abnormal fetal: acid-base balance heart rate or rhythm Fetal:

	acidemia bradycardia tachycardia Meconium in liquor 656.4 Intrauterine death [0,1,3] Fetal death: NOS after completion of 22 weeks gestation late Missed delivery Excludes: missed abortion (632) 656.5 Poor fetal growth [0,1,3] "Light-for-dates" "Placental insufficiency" "Small-for-dates" 656.6 Excessive fetal growth [0,1,3] "Large-for-dates" 656.7 Other placental conditions [0,1,3] Abnormal placenta Placental infarct Excludes: placental polyp (674.4) placentitis (658.4) 656.8 Other specified fetal and placental problems [0,1,3] Lithopedian 656.9 Unspecified fetal and placental problem [0,1,3] 657 Polyhydramnios [0,1,3] Requires fifth digit; valid digits are in [brackets] under each code. See beginning of section 650-659 for definitions. Use 0 as fourth digit for category 657 Hydramnios 658 Other problems associated with amniotic cavity and membranes Requires fifth digit; valid digits are in [brackets] under each code. See beginning of section 650-659 for definitions. Excludes: amniotic fluid embolism (673.1) 658.0 Oligohydramnios [0,1,3] Oligohydramnios without mention of rupture of membranes 658.1 Premature rupture of membranes [0,1,3] Rupture of amniotic sac less than 24 hours prior to the onset of labor 658.2 Delayed delivery after spontaneous or unspecified rupture of membranes [0,1,3] Prolonged rupture of membranes NOS Rupture of amniotic sac 24 hours or more prior to the onset of labor 658.3 Delayed delivery after artificial rupture of membranes [0,1,3] 658.4 Infection of amniotic cavity [0,1,3] Amnionitis Chorioamnionitis Membranitis

	Placentitis 658.8 Other [0,1,3] Amnion nodosum Amniotic cyst 658.9 Unspecified [0,1,3] 659 Other indiciations for care or intervention related to labor and delivery, not elsewhere classified Requires fifth digit; valid digits are in [brackets] under each code. See beginning of section 650-659 for definitions. 659.0 Failed mechanical induction [0,1,3] Failure of induction of labor by surgical or other instrumental methods 659.1 Failed medical or unspecified induction [0,1,3] Failed induction NOS Failure of induction of labor by medical methods, such as oxytocic drugs 659.2 Maternal pyrexia during labor, unspecified [0,1,3] 659.3 Generalized infection during labor [0,1,3] Septicemia during labor 659.4 Grand multiparity [0,1,3] Excludes: supervision only, in pregnancy (V23.3) without current pregnancy (V61.5) 659.5 Elderly primigravida [0,1,3] Excludes: supervision only, in pregnancy (V23.8) 659.6 Other advanced maternal age [0,1,3] Excludes: elderly primigravida (659.5) 659.8 Other specified indications for care or intervention related to labor and delivery [0,1,3] 659.9 Unspecified indication for care or intervention related to labor and delivery [0,1,3]

Appendix C. Definitions of Medical Terms Cited

This appendix contains definitions for other medical terms used in the report and testimonies from Stedman's Medical Dictionary. Especially [Holland:2002D] used several medical terms in his deposition. Here are their definitions as found in [Stedman:2000].

Angina: The definition of Angina in Stedman's Medical Dictionary [Stedman:2000] is "1. A severe, often constricting pain, usually referring to a. pectoris. Where a. pectoris is defined as, severe constricting pain in the chest, often radiating from the pericardium to a shoulder (usually left) and down the arm, due to schema of the heart muscle usually caused by coronary disease."

(Chronic) Cholecystitis: The definition of (Chronic) Cholecystitis in Stedman's Medical Dictionary [Stedman:2000] is "(chronic) inflammation of the gallbladder, usually secondary to lithiasis, with lymphocytic infiltration and fibrosis that may produce marked thickening of the wall."

Cough: The definition of Cough in Stedman's Medical Dictionary [Stedman:2000] is "1. A sudden explosive forcing of air through the glottis, occurring immediately on opening the previously closed glottis, excited by mechanical or chemical irritation of the trachea or bronchi or by pressure from adjacent structures."

Cystectomy: The definition of Cystectomy in Stedman's Medical Dictionary [Stedman:2000] is "1. Excision of the urinary bladder. 2. Excision of the gallbladder (cholecystectomy). 3. Removal of a cyst."

Dysphagia: The definition of Dysphagia in Stedman's Medical Dictionary [Stedman:2000] is "Difficulty is swallowing."

Fever: The definition of Fever in Stedman's Medical Dictionary [Stedman:2000] is "A complex physiologic response to disease mediated by pyrogenic cytokines and characterized by a rise in core temperature, generation of acute phase reactants, and activation of immune systems."

Hemoptysis: The definition of Hemoptysis in Stedman's Medical Dictionary [Stedman:2000] is "Spitting of blood derived from the lungs or bronchial tubes as a result of pulmonary or bronchial hemorrhage."

Joint Effusion: The definition of Joint Effusion in Stedman's Medical Dictionary [Stedman:2000] is "Increased fluid in synovial cavity of the joint."

Labor: The definition of Labor in Stedman's Medical Dictionary [Stedman:2000] is "The process of expulsion of the fetus and the placenta from the uterus."

Liposuction: The definition of Liposuction in Stedman's Medical Dictionary [Stedman:2000] is "Method of removing unwanted subcutaneous fat using percutaneously placed suction tubes."

Maternity: The definition of Maternity in Stedman's Medical Dictionary [Stedman:2000] is "Motherhood. Relating to or derived form the mother."

Meningitis: **The definition of Meningitis in Stedman's Medical Dictionary [Stedman:2000] is "Inflammation of the membranes of the brain or spinal cord."**

Nausea: The definition of Nausea in Stedman's Medical Dictionary [Stedman:2000] is "An inclination to vomit."

Pathogonomic: The definition of Pathogonomic in Stedman's Medical Dictionary [Stedman:2000] is "Characteristic or indicative of a disease; denoting especially one or more typical symptoms, findings, or pattern of abnormalities specific for a given disease and not found in any other condition."

Pathology: The definition of Pathology in Stedman's Medical Dictionary [Stedman:2000] is "The medical science, and specialty practice, concerned with all aspects of disease, but with special reference to the essential nature, causes, and development of abnormal conditions, as well as the structural and functional changes that result from disease processes."

Pneumonia: The definition of Pneumonia in Stedman's Medical Dictionary [Stedman:2000] is "Inflammation of the lung parenchyma characterized by consolidation of the affected part, the alveolar air spaces being filled with exudate, inflammatory cells, and fibrin. Most cases are due to infection by bacteria or viruses, a few to inhalation of chemicals or trauma to the chest wall, and a small minority to rickettsiae, fungi, and yeasts."

Sepsis: The definition of Sepsis in Stedman's Medical Dictionary [Stedman:2000] is "The presence of various pathogenic organisms, or their toxins, in the blood or tissues; septicemia is a common type."

Vomit: The definition of Vomit in Stedman's Medical Dictionary [Stedman:2000] is "1. To eject matter from the stomach through the mouth."

Appendix D. Claim Clusters for the `105 Patent

The `105 patent contains a collection of independent claims and their associated dependent claims forming claim clusters. Bold represents asserted claims.

Independent Claim	**Claim Clusters (Independent + Dependent) Claims**
1	**1**, **2**, 3, 13, 14, 15
4	**4**, **5, 6, 7, 8, 9**, 10, 11, **12**
16	**16, 17**, 18, 28, 29, 30
19	**19, 20, 21, 22, 23, 24, 25,** 26, **27**
31	31
32	32
33	33
34	**34, 35, 36, 37, 38, 39**, 40, 41, 42, **43**, 44, 45, 46
47	47, 48, 49, 50, 51
52	**52, 53, 54**
55	**55, 56, 57, 58, 59, 60**, 61, 62, **63**, 64, 65, 66
67	**67, 68, 69**
70	**70, 71, 72, 73, 74, 75**, 76, 77, **78**, 79, **80**, 81
82	82
83	83
84	84
85	**85, 86, 87, 88, 89**, 90, **91,** 92, **93**, 94, **95**, 96
97	97, 98, 99, 100, 101
102	**102**