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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/010,313	10/10/2008	6081786	1911-001	2580

20792 7590 06/22/2009

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED: 06/22/2009

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CENTRAL REEXAMINATION UNIT

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/010,313 and 90/009,204

PATENT NO. 6081786.

ART UNIT 3992.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/009,204	10/14/2008	6081786	SMA001	5799

20792 7590 06/22/2009

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EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED: 06/22/2009

Please find below and/or attached an Office communication concerning this application or proceeding.

**Notice of Intent to Issue
Ex Parte Reexamination Certificate**

Control No. 90/009,204 <i>and 9000 313</i>	Patent Under Reexamination 6081786	
Examiner Deandra M. Hughes	Art Unit 3992	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. Prosecution on the merits is (or remains) closed in this *ex parte* reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. Cf. 37 CFR 1.313(a). A Certificate will be issued in view of
 - (a) Patent owner's communication(s) filed: _____.
 - (b) Patent owner's late response filed: _____.
 - (c) Patent owner's failure to file an appropriate response to the Office action mailed: _____.
 - (d) Patent owner's failure to timely file an Appeal Brief (37 CFR 41.31).
 - (e) Other: _____.

Status of *Ex Parte* Reexamination:

 - (f) Change in the Specification: Yes No
 - (g) Change in the Drawing(s): Yes No
 - (h) Status of the Claim(s):
 - (1) Patent claim(s) confirmed: 1-66.
 - (2) Patent claim(s) amended (including dependent on amended claim(s)): _____
 - (3) Patent claim(s) cancelled: _____.
 - (4) Newly presented claim(s) patentable: _____.
 - (5) Newly presented cancelled claims: _____.
2. Note the attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."
3. Note attached NOTICE OF REFERENCES CITED (PTO-892).
4. Note attached LIST OF REFERENCES CITED (PTO/SB/08).
5. The drawing correction request filed on _____ is: approved disapproved.
6. Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the certified copies have
 - been received.
 - not been received.
 - been filed in Application No. _____.
 - been filed in reexamination Control No. _____.
 - been received by the International Bureau in PCT Application No. _____.

* Certified copies not received: _____.
7. Note attached Examiner's Amendment.
8. Note attached Interview Summary (PTO-474).
9. Other: _____.

/Deandra M Hughes/ Primary Examiner, Art Unit 3992		
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cc: Requester (if third party requester)

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EX PARTE REEXAMINATION NIRC

1. This is an *Ex Parte* Reexamination which has been merged with an *Ex Parte* Reexamination (90/010,313) proceeding of U.S. Patent No. 6,081,786 ("**Barry**").
2. Throughout this reexamination, the Patent Owner will be "**PO**". The third party requester for 90/009,313 will be "**EP-1**" and the third party requestor for 90/009,204 will be "**EP-2**".

References Cited in this Action

3. Shortliffe, E.H., "*Mycin: A Rule-Based Computer Program for Advising Physicians Regarding Antimicrobial Therapy Selection*," (Ph.D. thesis, Stanford University) (on file with Mathematical and Computer Sciences Library, Stanford University), Stanford Artificial Intelligence Laboratory Memo AIM-251, Computer Science Department Report No. STAN-CS-74-465, National Technical Information Service (NTIS) Technical Report No. AD-A001 373 (1974); ("**Shortliffe**")
4. Buchannan et al. Rule-Based Expert Systems: The MYCIN experiments of the Stanford Heuristic Programming Project (1984). ("**MYCIN**")
5. Siepman, J.P. and Bachman, J.W., "HTN-APT: Computer Aid in Hypertension Management," *Journal of Family Practice* 24:313-316(1987) ("**Siepman**")
6. Kulikowski, C.A. and Weiss, S.M., "Representation of Expert Knowledge for Consultation: The CASNET and EXPERT Projects," in *Artificial Intelligence in Medicine*, pp. 21-55 (Peter Szolovits ed., Westview Press, Boulder, CO) (1982) ("**Kulikowski**")
7. Miller, P.L. and Black, H.R., "Medical Plan-Analysis by Computer: Critiquing Pharmacologic Management of Essential Hypertension," *Computers and Biomedical Research* 17:38-54 (1984) ("**Miller**")
8. Evans, R.S., et al., "Development of an Automated Antibiotic Consultant," *M.D. Computing: Computers in Medical Practice* 10:17-22 (1993) ("**Evans 1993**")
9. Pazzani, M., et al., "CTSHIV: A Knowledge-Based System for the Management of HIV-Infected Patients," in *Intelligent Information Systems*, pp. 7-13 (Hojjat Adeli ed., IEEE Computer Society, Los Alamitos, CA) (1997) ("**Pazzani**")

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10. Hickam, D.H., *et al.*, "The Treatment Advice of a Computer-Based Cancer Chemotherapy Protocol Advisor," *Annals of Internal Medicine* 103:928-936 (1985) ("Hickam")

Claims Confirmed as Patentable

11. The following is a statement of reasons for confirming claims 1-66 as patentable over the prior art patents and publications cited in this merged reexamination.

Claims 1, 23, and 45 are the independent claims of the **Barry** patent.

Claim 1 claims, *inter alia*, a computer device comprising:

- a first knowledge base comprising a plurality of different therapeutic treatment regimens for said disease or medical condition;
- a second knowledge base comprising a plurality of expert rules for evaluating and selecting a therapeutic treatment regimen for said disease or medical condition;
- a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens.

Claim 23 claims, *inter alia*, a computing device comprising:

- a first knowledge base comprising a plurality of different therapeutic treatment regimens for said disease or medical condition;
- a second knowledge base comprising a plurality of expert rules for selecting a therapeutic treatment regimen for said disease or medical condition;
- a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens.

Claim 45 claims, *inter alia*, computer readable program code means for generating:

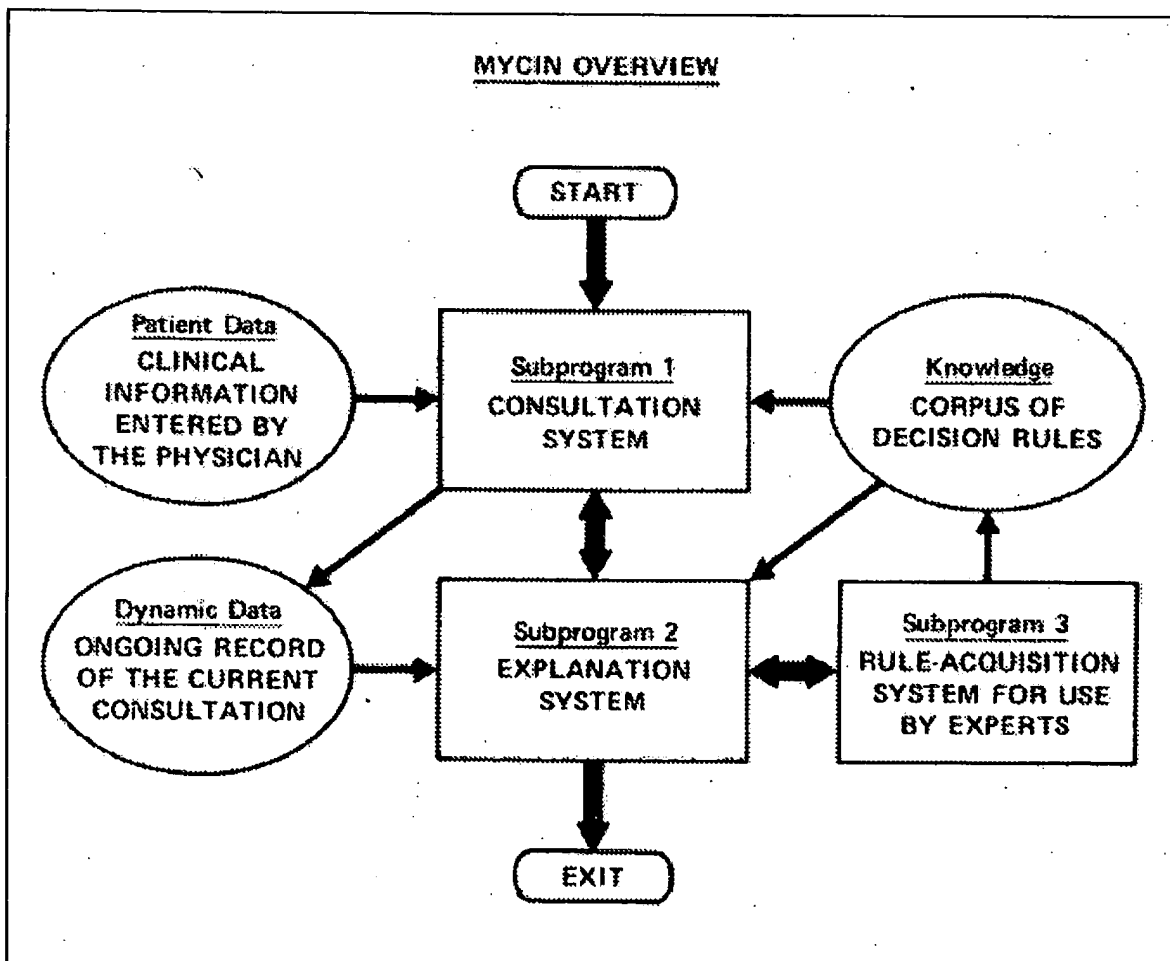
- a first knowledge base comprising a plurality of different therapeutic treatment regimens for said disease or medical condition;

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- a second knowledge base comprising a plurality of expert rules for selecting a therapeutic treatment regimen for said disease or medical condition;
- a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens.

The Shortliffe Reference

12. EP-1 references figure 1-1 of page 45, which is the graphic summary of the MYCIN System of the **Shortliffe** reference. (Request, pg. 32). The said figure 1-1 is reproduced below.



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EP-1 states that **Shortliffe** describes three components of the MYCIN system he developed: 1) a **Consultation System** which interacts with the physician and gives therapeutic advice; 2) an **Explanation System** which seeks to justify the program's advice, and 3) a **Rule Acquisition System** which accepts rules from experts and codes them for use during future consultation session. (Request, pg. 31). EP-1 alleges that **Shortliffe** "teaches the use of *multiple knowledge bases*, including different therapeutic regimens, expert rules, advisory information useful for treatment, and patient therapeutic treatment regiment history." (emphasis added; Request, pg. 32). Further, EP-1 states that

"Patentees may argue that Shortliffe refers to only a single knowledge base comprising expert rules, not three or four knowledge bases as required by the claims. This however would be a semantic difference. As shown in the charts below, Shortliffe 1974 unquestionably also discloses the knowledge bases of therapeutic treatment regimens and advisory information, simply using different terminology. And, as discussed above, the properly-construed claims do not require that the required knowledge bases be 'distinct' in any way." (Request, pg. 33, 1st ¶)

EP-1's rejection is not adopted because the above interpretation of **Shortliffe** is unpersuasive. On page 43 of the reference, **Shortliffe** unambiguously defined his use of the term 'knowledge base'. Below is an excerpt of page 43 with emphasis added.

"The discussion in Section IV.1 pointed out that there are four parts to the process of selecting antimicrobial therapy. MYCIN must accordingly follow each of these steps when giving advice to a physician. To reiterate, we have sought decision rules that allow the program to do the following:

- (a) decide whether the patient has a significant infection;
- (b) determine the likely identity of the offending organism;
- (c) decide what drugs are apt to be effective against the organism;

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- (d) choose the drug that is most appropriate given the patient's clinical condition;

Approximately 200 such decision rules have been identified to date. This corpus of rules is termed the 'knowledge-base' of the MYCIN System.

System knowledge must be contrasted with MYCIN's 'database'. MYCIN uses two kinds of data when it gives advice. Information about the patient under consideration is termed 'patient data'. These data are entered by the physician in response to computer-generated questions during the consultation. 'Dynamic data', on the other hand, are the data structures created by MYCIN during the consultation-deductions it has made and an ongoing record of how it has arrived at these conclusions. *This distinction between MYCIN's knowledge base and data-base should be understood because the terms are used in their specialized senses throughout this thesis.*

Since **Shortliffe** has unambiguously identified the approximately 200 decision rules, which had been identified to date, as the "knowledge base" of the system, **Shortliffe** does not *anticipate* claims 1, 23, and 45 because they claim three *distinct* knowledge bases. The Examiner considers a 'first' knowledge base, a 'second' knowledge base, and a 'third' knowledge base to be inherently distinct because the alternative would be for the knowledge bases to be indistinct thereby rendering the positive recitation of the terms 'first', 'second', and 'third' meaningless. In the claim charts for independent claims 1, 23, and 45 wherein EP-1 alleges that the said claims are anticipated by **Shortliffe**, EP-1 does not give the said 'first', 'second' and 'third' terms patentable weight. In addition, in the claim charts of claims 1, 23, and 45, EP-1 ignores **Shortliffe's** express definition of 'knowledge base' as applied throughout his thesis, thereby anticipating only a single knowledge base, i.e., the corpus of 200 decision rules. As a result, claims 1, 23, and 45 are confirmed as patentable over the **Shortliffe** reference.

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Nonetheless, the Examiner thoroughly considered whether one of ordinary skill in the art (e.g. a database engineer), at the time the invention was made, would have modified the *single* knowledge base of **Shortliffe's** MYCIN system to become the *three distinct* knowledge bases, which **Barry** claims as elements of his invention. The Examiner has concluded that such a modification would not have been obvious at the time the invention was made, absent impermissible hindsight, for the following reasons.

Returning to figure 1-1 above, the CORPUS OF DECISION RULES is the knowledge base of the system. One of ordinary skill in the art would readily understand that the other components of the system are *not* knowledge bases because they do not comprise a corpus of decision rules and **Shortliffe** expressly warns the reader to maintain the "distinction between MYCIN's knowledge-base and data-base." (**Shortliffe**, pg. 43, 3rd ¶). The component in **Shortliffe** that best meets **Barry's** claimed first knowledge base comprising "a plurality of different therapeutic treatment regimens for a known chronic disease or medical condition" would be the component of the MYCIN system that contains the list of drugs, i.e., the therapeutic regimens, which are apt to be effective against the offending organism. This would be **Shortliffe's** CONSULTATION SYSTEM, which **Shortliffe** disclose as that "portion of MYCIN *which asks questions, makes conclusions, and gives advice*" (**Shortliffe**, pg. 43, 3rd ¶), because "when MYCIN is through asking questions, it gives its therapeutic recommendation..." (**Shortliffe**, pg. 44, 4th ¶).

Since the CONSULTATION SYSTEM "makes conclusions and gives advice", one of ordinary skill in the art would have to move the decision rules *for making*

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conclusions and giving advice from the CORPUS OF DECISION RULES to the CONSULTATION SYSTEM in order for the CONSULTATION SYSTEM to become a 'knowledge base'. However, it is the 'third' knowledge base, which is distinct from the 'first' knowledge base, for the reasons set forth above, that gives advisory information. As a result, one of ordinary skill in the art would have to separate the 'advice giving' portion of the CONSULTATION SYSTEM knowledge base from the 'conclusion making' portion of the CONSULTATION SYSTEM to meet the claimed 'first' and 'third' knowledge bases of the **Barry** invention and the Examiner cannot identify any rationale, absent impermissible hindsight, for making such a modification. Accordingly, **claims 1, 23, and 45** are confirmed as patentable over **Shortliffe**, alone or in combination with the other cited prior art patents and publications of this merged re-examination.

The MYCIN Reference

13. This reference, which was submitted by **EP-2**, is a book written about the **MYCIN** system by Bruce G. Buchannan with Edward H. **Shortliffe**. The **Shortliffe** prior art publication submitted by **EP-1** also covers the **MYCIN** system. **Claims 1-66** are confirmed as patentable over the **MYCIN** reference, alone or in combination with the other cited prior art publications.

Figure 4-1, which is the structure of the **MYCIN** system, is reproduced below.

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The Structure of the MYCIN System

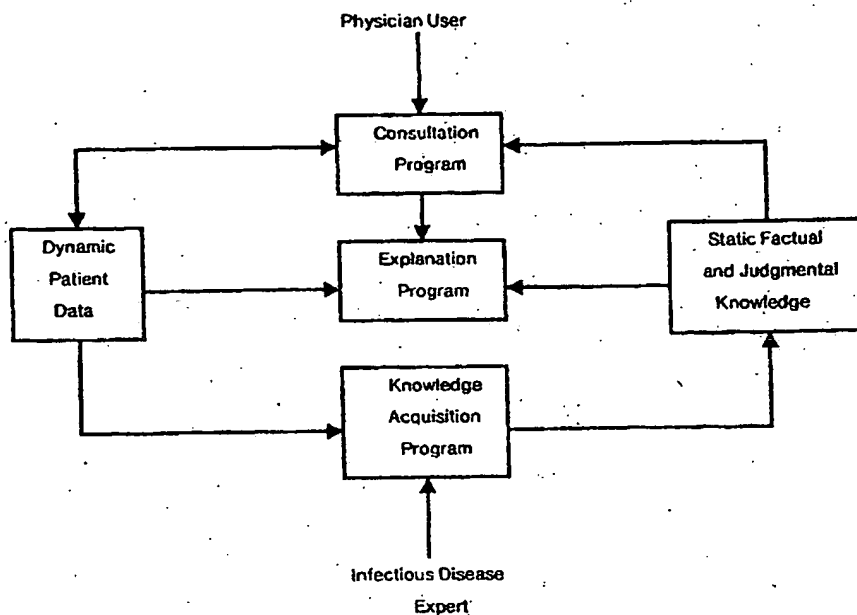


FIGURE 4-1 Organization of the MYCIN system. Arrows denote information flow between modules, knowledge base, and users.

Here, the CONSULTATION PROGRAM contains a list of different therapeutic treatment regimens for a disease or medical condition *and* it provides advisory information for one or more therapeutic treatment regimens. (see pg. 69 bottom of figure 4-2 for list of therapies and pg. 70, last line of figure 4-2 for advisory information, i.e. "modify dose in renal failure"). In Barry's patent **claims 1, 23, and 45**, the 'first' knowledge base contains the list of therapeutic regimens and the 'third' knowledge base contains the advisory information. In addition, MYCIN discloses that the CONSULTATION PROGRAM 'uses both system knowledge from the corpus of rules and patient data entered by the physician to generate *advice* for the user.' (emphasis added; pg. 78, 2nd ¶). MYCIN further discloses that "section 5.1 describes the corpus of

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rules and associated data structures and it provides a formal description of the rules used by **MYCIN**." (pg. 78, 3rd ¶). Also, **MYCIN** discloses that the "200 rules currently used by **MYCIN** are not explicitly linked in a decision tree or reasoning network. *This feature is in keeping with our desire to keep the system knowledge modular and manipulable.*" (emphasis added; pg. 85; 1st ¶).

In order to modify the structure disclosed in **MYCIN** to meet the claim limitations of claims 1, 23, and 45 of the **Barry** patent, at least the CONSULTATION PROGRAM has to be modified to incorporate the decision rules of the **MYCIN**'s knowledge base to become the claimed 'third' knowledge base.¹ However, **MYCIN** expressly warns against destroying the modularity of the knowledge base in order to keep the knowledge base manipulable. (pg. 85; 1st ¶). Consequently, **MYCIN** teaches against such a modification. Accordingly, claims 1-66 are confirmed as patentable over the **MYCIN** reference, alone or in combination with the other printed art patents and publications of this merged reexamination.

The Siepmann Reference

14. Claims 1-66 are confirmed as patentable over **Siepmann**. **Siepmann** does not disclose *three distinct* knowledge bases. Also, **Siepmann** does not disclose a 'third' knowledge base comprising advisory information useful for the treatment of a patient

¹ Since the CONSULTATION PROGRAM contains the list of therapeutic regimens and the advisory information, modifying the said PROGRAM to incorporate the relevant decision rules would merge the 'first' and 'third' knowledge bases into a single knowledge base. The Examiner considers the 'first', 'second', and 'third' knowledge bases to be distinct. Here, the said modification does not distinguish the 'first' knowledge base from the 'third' knowledge base. Accordingly, even if one of ordinary skill in the art would have incorporated the relevant decision rules into the CONSULTATION PROGRAM, the Examiner is unable to identify any rationale, absent impermissible hindsight, to separate the CONSULTATION PROGRAM into the claimed distinct 'first' and 'third' knowledge bases.

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with different constituents of said different therapeutic regimens. EP-1 cites page 315 of Siepman as disclosing the 'third' knowledge base comprising "the suitability of [the recommended] treatment options for the patient" and "the information necessary to prescribe any of the drugs." (see Request, pg. 75, 2nd box). However, the cited portions do *not* disclose the third knowledge base comprises advisory information useful for the treatment of a *patient with different constituents of said different therapeutic regimens*. Accordingly, claims 1-66 are confirmed as patentable over **Siepman** alone or in combination with the cited prior art patents and publications.

Further, EP-2 alleges that a third knowledge base comprising advisory information useful for the treatment of a *patient with different constituents of said different therapeutic regimens* is taught on pages 313 and 315 of the **Siepman** reference (EP Request, pgs. 117-118). In addition, the Examiner cannot identify any rationale, absent impermissible hindsight, to modify the invention of **Siepman** to comprise *three distinct knowledge bases*. Accordingly, claims 1-66 are confirmed as patentable over **Siepmann**, alone or in combination with the other prior art patents or publications cited in this merged reexamination.

The Kulikowski Reference

15. **Kulikowski** does not disclose a third knowledge base comprising *advisory information useful for the treatment of a patient with different constituents of said different therapeutic regimens* in combination with the other elements of independent claims 1, 23, and 45. EP-1 cites page 26 of **Kulikowski** as disclosing the third knowledge base. (Request, pg. 55; 2nd box). However, the cited disclosure does not

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disclose that the "additional feature of the system" comprises information useful for the *treatment of a patient with different constituents of said different therapeutic treatment regimens*.

Further, EP-1 cites pages 33-34 of **Kulikowski** as disclosing the third knowledge base. (Request, pg. 55; 2nd box). However, the cited portion does not disclose that the knowledge base is a *third* knowledge base. Pages 33-34 merely reference the entire CASNET model, which comprises a knowledge base, i.e. the General Class of Therapies and the second knowledge base, i.e. the restriction rules R1-R3, but does not disclose a *third distinct* knowledge base. Further, the Examiner cannot identify any rationale, absent impermissible hindsight, to modify the invention of **Kulikowski** to comprise *three distinct knowledge bases*. Accordingly, claims 1-66 are confirmed as patentable over **Kulikowski**, alone or in combination with the other prior art patents or publications cited in this merged reexamination.

The Miller Reference

16. **Miller** does not disclose a *third knowledge base* comprising advisory information useful for the treatment of a patient *with different constituents of said different therapeutic regimens*. EP-1 cites pages 38 and 44-45 of **Miller** as disclosing the *third* knowledge base comprising new drugs and new treatment modalities wherein the **third** knowledge base mentions relevant topical issues all in the context of discussing an approach to a particular patient's care. (Request, pg. 63, 2nd box). However, the cited portions do not disclose that the *third* knowledge base comprises advisory information useful for the treatment of a *patient with different constituents of said different*

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therapeutic regimens. Further, the Examiner cannot identify any rationale, absent impermissible hindsight, to modify the invention of **Miller** to comprise *three distinct knowledge bases*. Accordingly, **claims 1-66** are confirmed as patentable over **Miller**, alone or in combination with the other prior art patents or publications cited in this merged reexamination.

The Evans 1993 Reference

17. **Evans 1993** does not disclose *three distinct knowledge bases*. The knowledge bases cited by EP-1 (Request pgs. 83-84) are not disclosed as distinct databases. In addition, **Evans 1993** specifically teaches that "because the information is coded, a knowledge base can analyze and monitor patient care." (emphasis added; pg. 18) Further, the Examiner cannot identify any rationale, absent impermissible hindsight, to modify the invention of **Evans 1993** to comprise *three distinct knowledge bases*. Accordingly, **claims 1-66** are confirmed as patentable over **Evans 1993**, alone or in combination with the other prior art patents or publications cited in this merged reexamination.

The Pazzani Reference

18. **Pazzani** does not disclose *three distinct knowledge bases*. The knowledge base cited by EP-1 (Request pg. 93, 3rd box) are not disclosed as distinct knowledge bases. Notably, **Pazzani** specifically teaches that "CTSHIV contains a knowledge base..." (pg. 7) and "CTSHIV uses its knowledge base..." (pg. 8) thereby expressly disclose a *single* knowledge. Further, the Examiner cannot identify any rationale, absent impermissible hindsight, to modify the invention of **Pazzani** to comprise *three distinct knowledge*

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bases. Accordingly, claims 1-66 are confirmed as patentable over **Pazzani**, alone or in combination with the other prior art patents or publications cited in this merged reexamination.

The Hickman Reference

19. **Hickman** does not disclose *three distinct knowledge bases*. The knowledge bases cited by **EP-1** are not disclosed as distinct knowledge bases. (Request pg. 103). In addition, *Hickman* does not disclose a knowledge base comprising advisory information useful for the treatment of a patient *with different constituents of said different therapeutic regimens*. Further, the Examiner cannot identify any rationale, absent impermissible hindsight, to modify the invention of **Hickman** to comprise *three distinct knowledge bases*. Accordingly, claims 1-66 are confirmed as patentable over **Hickman**, alone or in combination with the other prior art patents or publications cited in this merged reexamination.

Conclusion

20. All correspondence relating to this ex parte reexamination proceeding should be directed:

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22. Any inquiry concerning this communication or earlier communications from the examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

/Deandra M. Hughes/

Deandra M. Hughes
Primary Examiner
Central Reexamination Unit 3992
(571) 272-6982

Conferees:

ESK
CJD