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CONTROL NO.	FILING DATE	PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
95/001,088	10/10/08	6188988	1911-001

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EXAMINER

HUGHES, DEANDRA

ART UNIT PAPER

3992

DATE MAILED:
MAILED

JUN 11 2009

**INTER PARTES REEXAMINATION
COMMUNICATION**

CENTRAL REEXAMINATION UNIT

BELOW/ATTACHED YOU WILL FIND A COMMUNICATION FROM THE UNITED STATES PATENT AND TRADEMARK OFFICE OFFICIAL(S) IN CHARGE OF THE PRESENT REEXAMINATION PROCEEDING.

All correspondence relating to this *inter partes* reexamination proceeding should be directed to the Central Reexamination Unit at the mail, FAX, or hand-carry addresses given at the end of this communication.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/001,088	10/10/2008	6188988	1911-001	2615

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EXAMINER

HUGHES, DEANDRA M

ART UNIT PAPER NUMBER

3992

MAIL DATE DELIVERY MODE

06/11/2009

PAPER

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

The time period for reply, if any, is set in the attached communication.

**ACTION CLOSING PROSECUTION
(37 CFR 1.949)**

Control No.	Patent Under Reexamination	
90/009,213 ; 95/001,088	6188988	
Examiner	Art Unit	
Deandra M. Hughes	3992	

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

Responsive to the communication(s) filed by:

Patent Owner on _____

Third Party(ies) on IP-3PR 10/10/08 on and EP-3PR on 10/14/08 and

Patent owner may once file a submission under 37 CFR 1.951(a) within 1 month(s) from the mailing date of this Office action. Where a submission is filed, third party requester may file responsive comments under 37 CFR 1.951(b) within 30-days (not extendable- 35 U.S.C. § 314(b)(2)) from the date of service of the initial submission on the requester. **Appeal cannot be taken from this action.** Appeal can only be taken from a Right of Appeal Notice under 37 CFR 1.953.

All correspondence relating to this inter partes reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of this Office action.

PART I. THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892
2. Information Disclosure Citation, PTO/SB/08
3. _____

PART II. SUMMARY OF ACTION:

- 1a. Claims 1-66 are subject to reexamination.
- 1b. Claims _____ are not subject to reexamination.
2. Claims _____ have been canceled.
3. Claims 1-66 are confirmed. [Unamended patent claims]
4. Claims _____ are patentable. [Amended or new claims]
5. Claims _____ are rejected.
6. Claims _____ are objected to.
7. The drawings filed on _____ are acceptable are not acceptable.
8. The drawing correction request filed on _____ is: approved. disapproved.
9. Acknowledgment is made of the claim for priority under 35 U.S.C. 119 (a)-(d). The certified copy has:
 been received. not been received. been filed in Application/Control No _____
10. Other _____

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MERGED REEXAMINATION ACTION CLOSING PROSECUTION

1. This is an *Inter Partes* Reexamination ("IP") which has been merged with an *Ex Parte* Reexamination ("EP") Proceeding of U.S. Patent No. **6,188,988** ("**Barry**"). (see Decision to Merge Proceedings mailed Mar. 19, 2008).

In the Order for reexamination (IP 95/001,088 dated 1/7/09), the Examiner found that only the consideration of **Shortliffe** in combination with **Perry** presented a Substantial New Question of Patentability ("SNQ") as to **claims 13-19, 22, 35-41, 44, 56-62, and 65**. (IP Order dated 1/7/09; pgs. 7-8).

However, EP proceeding (90/009,213), which found that the consideration of **MYCIN** and **Siepman** presented an SNQ as to **claims 1-66**, has been merged with IP proceeding (95/001,088). In the IP proceeding, **MYCIN** was *not* submitted as a prior art publication. On the other hand, **Siepman** was submitted by both the IP requester ("IP-3PR") and the EP requester ("EP-3PR") as a prior art publication that presented an SNQ as to at least the independent **claims 1, 23, and 45**.

In the EP proceeding, **Siepman** was found to present an SNQ as to **claims 1, 23, and 45** by Examiner Fleming. (EP Order dated 11/29/08; pg. 5)

In the IP proceeding, **Siepman** was found *not* to present an SNQ as to **claims 1, 23, and 45** by Examiner Hughes. (IP Order dated 07/07/08; pg. 7)

This split is resolved in the instant action because jurisdiction over **claims 1-66** of the merged proceeding has been passed to the Examiner via the merger of the IP and EP proceedings. Since jurisdiction *over the merged proceeding* (see Decision to Merge dated 3/19/09; pg. 5) has been forwarded to the Examiner, the Examiner will examine **claims 1-66** for patentability over the following prior art publications.

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- (A) IP-3PR alleges that **Siepmann** anticipated claims 1, 5, 6, 8, 12-14, 20-23, 27, 28, 30, 34-36, 42-45, 49, 51, 55-57, and 63-66.
- (B) IP-3PR alleges that **Shortliffe** in combination with **Perry** rendered obvious claims 13-19, 22, 35-41, 44, 56-62, and 65.
- (C) EP-3PR alleges that **MYCIN**, alone or in combination, anticipates or makes obvious, claims 1-66.
- (D) EP-3PR alleges that **Siepmann**, alone or in combination, anticipates or makes obvious, claims 1-66.

The remaining prior art publications submitted by IP-3PR were found not present an SNQ as to claims 1-66 of the **Barry** patent. (IP Order dated 11/29/08; pg. 7)

Accordingly, the said remaining art publications are not addressed in the instant office action.

References Cited in this Action

- 2. 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**")
- 3. Buchannan et al. Rule-Based Expert Systems: The MYCIN experiments of the Stanford Heuristic Programming Project (1984). ("**MYCIN**")
- 4. Siepmann, J.P. and Bachman, J.W., "HTN-APT: Computer Aid in Hypertension Management," *Journal of Family Practice* 24:313-316(1987) ("**Siepmann**")
- 5. Perry, C.A., "Knowledge bases in medicine: a review" *Bulletin of the Medical Library Association* 78:271-282 (1990) ("**Perry**")

Typographical Error

- 6. A typographical error in claim 44 is noted because it claims "a system according to claim further comprising...". It appears as if the said statement is a typographical error wherein it should read "a system according to claim [23] further comprising"

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because said claim dependency is consistent with analogous claim 22, which depends upon claim 1.

Summary of this Action

7. Claims 1-66 are confirmed as patentable.

Reasons for Confirmation of Claims as Patentable

8. The following are statements of reasons for confirming the patentability of claims 1-66.

The SHORTLIFFE Reference

9. Claims 1-66 are confirmed as patentable over **Shortliffe**, alone or in combination with **Perry**.

The following is a statement for the reasons for confirming claims 1-66 over **Shortliffe**, alone or in combination with **Perry**.

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;

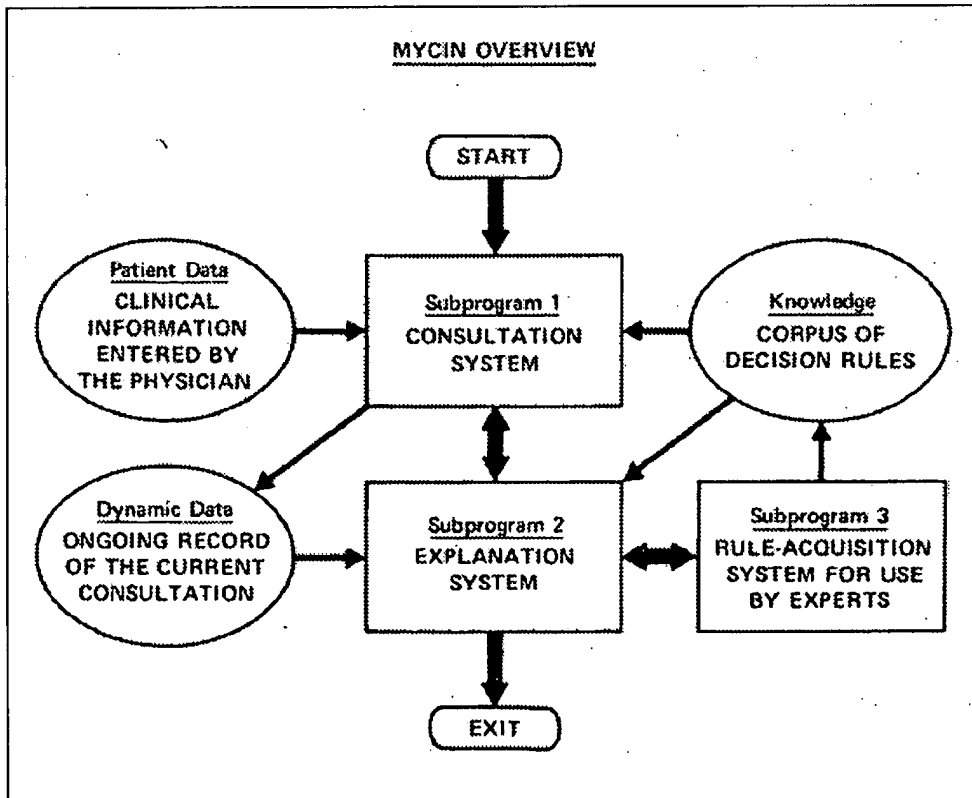
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- a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens.

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;
- 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.

IP-3PR references figure 1-1 of page 45, which is the graphic summary of the MYCIN System of the **Shortliffe** reference. (Request, pg. 31). The said figure 1-1 is reproduced below.



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IP-3PR 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). IP-3PR 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, IP-3PR 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 ¶)

IP-3PR'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;

- (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. (see also Order mailed 1/7/09; pg. 9). In the claim charts for independent claims 1, 23, and 45 wherein IP-3PR alleges that the said claims are anticipated by **Shortliffe**, IP-3PR does not give the said 'first', 'second' and 'third' terms patentable weight. In addition, in the claim charts of claims 1, 23, and 45, IP-3PR 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, IP-3PR's rejection of claims 1, 23, and 45 as being anticipated by **Shortliffe** has not been adopted.

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

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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 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

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'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.

Perry teaches that "largely due to the success of MYCIN, rule-based systems continue to evolve...clearly, it is easier to adapt existing frameworks than to begin the process entirely from the beginning." (pg. 275, col. 2, lines 37-41). However, **Perry** does not teach *how* to adapt the said existing frameworks. Absent impermissible hindsight, the Examiner cannot identify any rationale for one of ordinary skill in the art making the modification of, at least, separating the 'advice giving' portion of the CONSULTATION SYSTEM from the 'conclusion making' portion of the said system. Further, **IP-3PR** has not submitted any teachings of prior art patents and publications to support the said modification. Accordingly, **claims 1, 23, and 45** are confirmed as patentable over **Shortliffe**, alone or in combination with **Perry**.

The MYCIN Reference

10. This reference, which was submitted by **EP-3PR**, is a book written about the **MYCIN** system by Bruce G. Buchannan with Edward H. **Shortliffe**. The **Shortliffe** prior art publication submitted by **IP-3PR** 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.

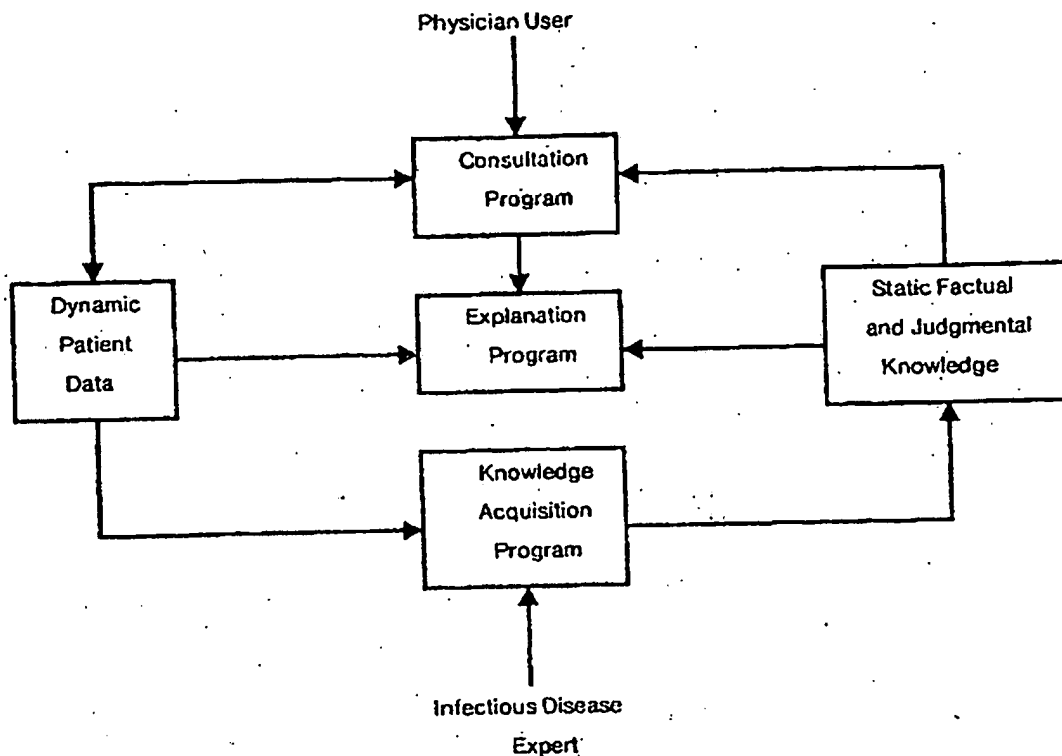


FIGURE 4-1 Organization of the MYCIN system. Arrows denote information flow between modules, knowledge base, and users.

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

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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 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.

The SIEPMAN Reference

11. Claims 1-66 are confirmed as patentable over **Siepmann**. **Siepmann** does not disclose three distinct knowledge bases. The knowledge databases cited by **IP-3PR** (see Request pgs. 79-80) are not disclosed as *distinct* databases. In addition, **Siepmann** does not disclose a 'third' knowledge base comprising advisory information useful for

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

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the treatment of a patient *with different constituents of said different therapeutic regimens*. IP-3PR 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. 80).

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 therapeutic regimens*. Accordingly, IP-3PR's proposed rejection of claims 1, 5-6, 8, 12-14, 20-23, 27-28, 30, 34-36, 42-45, 49, 51, 55-57, and 63-66 as being anticipated by Siepman are not adopted.

Further, for the reasons set forth above EP-3PR's proposed rejections of claims 1-66 over Siepman, alone or in combination with other prior art publications, is not adopted. EP-3PR 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). Since EP-3PR alleges that the said claim element is taught by Siepman, EP-3PR does not attempt to cure the said missing disclosure with a teaching from a secondary reference. Accordingly, claims 1-66 are confirmed as patentable over Siepman because Siepman does not anticipate or make obvious 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 features set forth in the independent claims.

is unable to identify any rationale, absent impermissible hindsight, to separate the CONSULTATION PROGRAM into the claimed distinct 'first' and 'third' knowledge bases.

Conduct of this Merged Proceeding

12. The same claims must be maintained in both proceedings. The claims are identical in both proceedings. Patent Owner is required to maintain the same claims (and specification) in both files throughout the merged proceeding.

13. Governing Regulations for the merged proceeding:

Pursuant to CFR 1.989(b), the merged proceeding is governed by 37 CFR 1.902 through 1.997, except that that the rights of **EP-3PR** are governed by 37 CFR 1.510 through 1.560.

14. Papers mailed/filed:

All papers mailed by the Office throughout the merged proceeding will take the form of a single action which applies to both proceedings. All papers issued by the Office, or filed by the Patent Owner and the **IP-3PR**, will contain the identifying data for both files and will be physically entered in each reexamination file. All papers filed by the Patent Owner and the **IP-3PR** must consist of a single paper, filed in duplicate, each bearing a signature and identifying data for both files, for entry into each file.

All papers filed by the Patent Owner and Third Party Requesters should be directed by Mail to:

By Mail to: Mail Stop *Inter Partes* Reexam
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EFS-Web offers the benefit of quick submission to the particular area of the Office that needs to act on the correspondence. Also, EFS-Web submissions are “soft scanned” (i.e., electronically uploaded) directly into the official file for the reexamination proceeding, which offers parties the opportunity to review the content of their submissions after the “soft scanning” process is complete.

15. Amendments:

The filing of any amendments to the drawings, specification or claims must comply with 37 CFR 1.943, which incorporates the provisions of 37 CFR 1.530, and the guidelines of MPEP § 2666.01, which in turn references the guidelines of MPEP § 2250.

37 CFR 1.121 does not apply to amendments in reexamination. Accordingly, clean copies of the amended claims are not required and are not to be submitted; rather amendments are to be presented via markings pursuant to paragraph 37 CFR 1.530(0, except that a claim should be canceled by a statement canceling the claim, without presentation of the text of the claim.

Pursuant to 37 CFR 1.530(i), **all amendments must be made relative to the patent specification**, including the claims, and drawings, which are in effect as of the date of filing the request for reexamination. *Amendments are not to be made relative to previous amendments.* Thus, for all amendments, all words not appearing in the patent are always underlined, and only words being deleted from the patent appear in brackets.

16. Fees:

Where a paper is filed that requires payment of a fee (e.g., petition fee, excess claims fee, extension of time fee, appeal fee, brief fee, oral hearing fee), only a single fee need be paid. For example, only one fee need be paid for any patent owner's appellant brief (or that of the *inter partes* reexamination requester) which may be filed, even though the brief relates to merged multiple proceedings, and copies must be filed (as pointed out above) for each file in the merged proceeding.

Conclusion

17. This is an ACTION CLOSING PROSECUTION (ACP); see MPEP § 2671.02.

Pursuant to 37 CFR 1.951(a), the Patent Owner may once file written comments limited to the issues raised in the reexamination proceeding and/or present a proposed amendment to the claims which amendment will be subject to the criteria of 37 CFR

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1.116 as to whether it shall be entered and considered. Such comments and/or proposed amendments must be filed within a time period of 30 days or one month (whichever is longer) from the mailing date of this action. Where the Patent Owner files such comments and/or a proposed amendment, the **IP-3PR** may once file comments under 37 CFR 1.951(b) responding to the Patent Owner's submission within 30 days from the date of service of the Patent Owner's submission on the **IP-3PR**.

18. If the Patent Owner does not timely file comments and/or a proposed amendment pursuant to 37 CFR 1.951(a), then the **IP-3PR** is precluded from filing comments under 37 CFR 1.951(b).

19. Appeal **cannot** be taken from this action, since it is not a final Office action.

20. 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

June 8, 2009

Conferees:

ALBERT J. GAGLIARDI
PRIMARY EXAMINER
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