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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/010,599	07/10/2009	6188988	1911-001	2664

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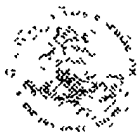
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EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED: 12/22/2009

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



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EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/010,599.

PATENT NO 6188988

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)).

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

Control No.	Patent Under Reexamination	
90/010,599	6188988	
Examiner	Art Unit	
Deandra M. Hughes	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: 29 October 2009.
 - (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

cc. Requester (if third party requester)

EX PARTE REEXAMINATION NIRC

1. This is the third reexamination of U.S. Patent No. **6,188,988** ("**Barry**"). Pending proceedings 90/009,213 and 95/001,008 have been merged.
2. In the Order for reexamination the Examiner found that only the consideration of **Lau**, alone or in combination, presented a Substantial New Question of Patentability ("SNQ") as to **claims 1, 4-23, 26-45, and 48-66**.

The decision to reexamine any claim for which reexamination has not been ordered lies within the sole discretion of the Office, to be exercised based on the individual facts and situation of each individual case. 35 USC §303a, MPEP §2240. In the interest of special dispatch, the Examiner chooses to reexamine **claims 1-66** of the **Barry** patent.

References Cited in this Action

3. Lau, Francis. *A clinical decision support system prototype for cardiovascular intensive care*. International Journal of Clinical Monitoring and Computing. 11:157-69. 1994. ("**Lau**")
4. Declaration of Edward H. Shortliffe, Ph.D. filed July 20, 2009. ("**Shortliffe Declaration**")

Reasons for Confirmation of Claims as Patentable

5. The following is a statement for the reasons for confirming claims 1-66 over Lau, alone or in combination.

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;
- 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.

Lau does not disclose or suggest, inter alia, *at least three distinct knowledge bases wherein the third knowledge base comprises advisory information useful for the treatment of a patient with different constituents of the claimed different therapeutic treatment regimens* in combination with the other features set forth in the claims.

Lau discloses a study wherein the objective was to develop a knowledge-based, decision-support system prototype to facilitate hemodynamic management of CVICU patients and to validate the prototype's performance against historical cases. (pg.158, col. 2, 2nd ¶). Knowledge expert acquisition sessions were conducted with two expert Physicians to critique 26 historical cases. (pg. 159, col. 1, 2nd ¶) One group, with 410 interventions instituted was used as the 'learning cases' from which *the knowledge base* was constructed. (Id., emphasis added).

In **Lau**, a conceptual decision framework was developed to provide the basis for therapeutic management of hypovolemic hypotension. The major components of this framework are *its knowledge base and reasoning process*. (pg. 159, col 2, 1st ¶, emphasis added).

The **Shortliffe Declaration** alleges the following as reproduced below.

D. *Lau 1994*

37 The *Lau 1994* reference, entitled "A clinical decision support system prototype for cardiovascular intensive care" describes the design and implementation of an expert system for the therapeutic management of hypovolemic hypotension in the ICU setting²⁴ Lau expressly states that its knowledge is divided into multiple knowledge bases

The knowledge elicited from the expert sources - target ranges, physiologic patterns, clinical conditions, intervention strategies, therapeutic drug-dosage responses, and therapeutic and reverse protocols - was formalized as the basis of the decision framework. The structure and usage of selected *knowledge bases* are briefly described below²⁵

38 *Lau 1994* describes no less than *seven* different knowledge bases in detail, including "Intervention choices,"²⁶ which directly corresponds to Barry's "first knowledge base," a "plurality of different therapeutic treatment regimens for said disease or medical condition "

Intervention choices. An intervention choice can be a specific diagnostic test or therapeutic agent. In this study, a set of therapeutic protocols was formalized to manage fluid replacement and bleeding. The protocols are invoked if 'reduce-volume-deficit' or 'stopactive-bleeding' was selected as the intervention strategy. The selection of the intervention choice, in this case an agent, from the protocols is contingent upon several factors. For bleeding, anti-coagulopathy agents such as protamine, cryoprecipitate, platelets and freshfrozen plasma are chosen according to PT, PTT and PLT results. In fluid replacement, the type of crystalloid or colloid used depends on the levels of serum Na, OSM, ICT and HB. The amount of fluid required is computed using the net-difference scoring and ranking algorithms. Critiquing rules were developed to determine the intervention choice when the patient is on vasoactive therapy or there is a change in the inotropic or vasoactive therapy.²⁷

39. Moreover, at least the "Drug-dosage response tables" and "Net difference scoring" knowledge bases each directly correspond to Barry's "second knowledge base . . . of expert rules for evaluating and selecting a therapeutic treatment regimen "

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The **Shortliffe Declaration** alleges the 1st knowledge base is the disclosed *Intervention Choices* (Lau, pg. 161, col. 2). Next, the **Shortliffe Declaration** alleges the 2nd knowledge base is the disclosed *Drug-dosage response tables* or the disclosed *Net Difference Scoring* (Lau, pg. 162) The **Shortliffe Declaration** is silent as to claimed 3rd knowledge base comprising *advisory information useful for the treatment of a patient with different constituents of the claimed different therapeutic treatment regimens*.

Nonetheless, the Examiner thoroughly considered whether it would have been obvious to one of ordinary skill in the art (e.g. an database engineer), at the time the invention was made to modify the disclosed decision framework with a knowledge base comprising *advisory information useful for the treatment of a patient with different constituents of the claimed different therapeutic treatment regimens*.

The **Shortliffe Declaration** alleges **Lau** teaches "no less than seven distinct knowledge bases." These alleged knowledge bases are: (1) reference/target ranges, (2) physiological patterns, (3) clinical patterns, (4) intervention strategies, (5) intervention choices, (6) drug-dosage response tables, and (7) net difference scoring. (Lau, pgs. 160-162). The **Shortliffe Declaration** alleges the claimed 1st knowledge base corresponds to "(5) *intervention choices*". The **Shortliffe Declaration** also alleges the claimed 2nd knowledge base corresponds to "(6) *drug-dosage response tables*" or "(7) *net difference scoring*". Further, third party requester ("3PR") alleges "(2) *physiological patterns*" and "(4) *intervention strategies*" can meet the claimed 2nd knowledge base." (Request, pg. 117, 5th ¶). As such, alleged knowledge bases "(1)

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reference/target ranges" and "(3) *clinical patterns*" are left to be modified via a teaching or suggestion from either **Lau** or a secondary reference to meet the claimed limitation of a 3rd *knowledge base comprising advisory information useful for the treatment of a patient with different constituents of the claimed different therapeutic treatment regimens.*¹

However, one of ordinary skill in the art would not modify the decision support system of **Lau** to include a distinct knowledge *comprising advisory information useful for the treatment of a patient with different constituents of the claimed different therapeutic treatment regimens.* As explained above, the only alleged knowledge bases left to modify in the disclosure of **Lau** is "(1) *reference/target ranges*" and "(3) *clinical patterns*". The alleged *reference/target ranges* 'knowledge' base is merely four pairs of numeric low-high thresholds which were defined for each parameter as warning, alert, critical, and physiological limit, respectively. (pg. 160, col. 2, last ¶). One of ordinary skill in the art would not modify the *reference/target ranges* to form a 3rd *knowledge base comprising advisory information useful for the treatment of a patient with different constituents of the claimed different therapeutic treatment regimens* because a

¹ The Examiner notes that the 3PR provided a substantially different interpretation of **Lau** in the instant reexamination than that was proposed in a previous reexamination (90/009,213).

In the 90/009,213 proceeding 3PR alleges **Lau**'s "(5) Intervention Choices" meets the claim limitation of all three distinct knowledge bases. (Request of 90/009,213; pgs. 30-31). Here, the 1st knowledge base is limited to Intervention Choices and 3PR alleges at least 4 other databases meet the claimed 2nd knowledge base. 3PR further admits **Lau** does not disclose the claimed 3rd knowledge base (Request, pg. 119, 1st box, last ¶)

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database engineer would not recognize four pairs of numeric high-low thresholds to be a 'knowledge base'.

Further, **Lau** discloses the *clinical patterns* section of the system is designed to match each known pattern to one or more clinical conditions. (pg. 161, col. 2, 1st ¶). However, the claimed 3rd knowledge base comprises advisory information useful for the treatment of a patient with different constituents of the different therapeutic treatment regimens of the 1st knowledge base.² 3PR alleges **Lau's** *Intervention Choices* meets the claimed 1st knowledge base. However, nothing in **Lau** or a secondary reference teaches or suggests modifying the clinical patterns section of the system to comprise advisory information useful for the treatment of a patient with different constituents of the different specific diagnostic tests or therapeutic agents within the *Intervention Choices* 'knowledge' base. (see **Lau**, pg. 161, 2nd col., last ¶)

For at least these reasons, **claims 1-66** of the Barry patent are confirmed as patentable over **Lau**, alone or in combination with the cited prior art references.

Conclusion

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

By Mail to: Mail Stop Ex Parte Reexam
Attn: Central Reexamination Unit
Commissioner for Patents
United States Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

² This is due to the antecedent basis of the claimed phrase 'of said different therapeutic treatment regimens.'

By FAX to: (571) 273-9900
Central Reexamination Unit

By hand: Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

7. Registered users of EFS-Web may alternatively submit such correspondence via the electronic filing system EFS-Web, at:

<https://portal.uspto.gov/authenticate/authenticateuserlocalepf.html>.

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.

8. 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:

/A. J. G./

Examiner, Art Unit 3992

ESK

December 22, 2009