IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: Stephen J. Brown   Atty. Docket No.: 06-0667

Serial No.: 11/668,103   Filing Date: January 29, 2007

Confirmation No.: 3263   Customer No.: 60683

Examiner: Abdullahi Elmi Salad   Group Art Unit: 2456

Title of Invention: DRUG MARKETING AND DEVELOPMENT TOOL

AMENDMENT UNDER 37 C.F.R. §1.116

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This amendment is in response to the Office Action mailed November 2, 2011, setting a

three-month statutory period for response. Therefore, this amendment is timely filed. The

Applicants respectfully request that the Examiner favorably consider the following remarks and

amend the present application in the manner set forth in this amendment:

IN THE CLAIMS:

Please substitute the following claims for the same numbered claims in the application:

1.   (Currently Amended) A system for remotely querying an individual regarding effects of a pharmaceutical drug, said system comprising:

a communications channel;

a remote interface device that generates data queries to be answered by the individual;

a server that generates one or more computer executable commands based on said data queries; and

a remote hand-held apparatus that receives said one or more computer executable commands from said server over said communications channel and comprising at least one device jack that directly connects the remote hand-held apparatus with a monitoring device, wherein said computer executable commands represent said data queries related to said pharmaceutical drug developed by a pharmaceutical drug manufacturer, wherein said remote hand-held apparatus comprises a processor that executes said computer executable commands to cause communication of at least one of said data queries to said individual, and wherein said server generates said computer executable commands using a script generator and one or more templates,

wherein said remote hand-held apparatus further (i) receives responses to said at least one of said data queries from said individual, and (ii) transmits said responses to said server,

wherein said remote hand-held apparatus further (i) receives measurements from said monitoring device, and (ii) transmits said measurements to said server, and

wherein said server receives said responses and said measurements and generates a report

to be sent back to said remote hand-held apparatus.

2.　　(Previously Presented) The system of claim 1, further comprising a user interface

operatively connected to said remote hand-held apparatus, wherein said user interface comprises

a display unit and an audio transducer that audibly communicate with said individual.

3.　　(Previously Presented) The system of claim 2, wherein said audio transducer audibly

notifies said individual of said data queries.

4.　　(Original) The system of claim 1, wherein said communications channel comprises the

Internet.

5.　　(Original) The system of claim 1, wherein said responses comprise any of audible

responses, data entry responses, and direct responses.

6.　　(Previously Presented) The system of claim 1, wherein said monitoring device is

operatively connected to said remote hand-held apparatus through said device jack.

7.　　(Previously Presented) The system of claim 6, wherein said monitoring device monitors

any of blood glucose, respiratory flow, blood pressure, weight, and pulse rate of said individual.

8.　　(Previously Presented) The system of claim 6, wherein said monitoring device monitors

any of an efficacy, side effects, and quality of life impact of said pharmaceutical drug on said

individual.

9.   (Currently Amended) A system for remotely querying an individual regarding effects of a pharmaceutical drug, said system comprising:

a remote interface device that generates data queries to be answered by the individual;

a server that generates one or more computer executable commands based on said data queries;

a communication component that receives said computer executable commands from said server, wherein said computer executable commands represents said data queries related to said pharmaceutical drug marketed by a pharmaceutical drug marketer and wherein said server generates said computer executable commands using a script generator and one or more templates;

a user interface device comprising a display unit, an input device jack that receives input from a monitoring device, and an audio transducer that audibly notifies said individual of said data queries; and

a processor that executes said computer executable commands to cause communication of at least one of said data queries to said individual,

wherein said communication component (i) receives responses to said at least one of said data queries from said individual, and (ii) transmits said responses to said server,

wherein said communication component further (i) receives measurements from said monitoring device, and (ii) transmits said measurements to said server; and

wherein said server receives said responses and said measurements and generates a report to be sent back to said communication component.

10.   (Original) The system of claim 9, wherein said server and said communication component are linked through the Internet.

11.   (Original) The system of claim 9, wherein said responses comprise any of audible responses, data entry responses, and direct responses.

12.   (Previously Presented) The system of claim 9, wherein said monitoring device is operatively connected to said device jack.

13.   (Previously Presented) The system of claim 12, wherein said monitoring device monitors any of blood glucose, respiratory flow, blood pressure, weight, and pulse rate of said individual.

14.   (Previously Presented) The system of claim 12, wherein said monitoring device monitors any of an efficacy, side effects, and quality of life impact of said pharmaceutical drug on said individual.

15.   (Currently Amended) A method for remotely querying an individual regarding effects of a pharmaceutical drug, said method comprising:

        generating data queries to be answered by the individual through a remote interface device;

        generating one or more computer executable commands based on said data from set of queries using a script generator and one or more templates;

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sending the generated computer executable commands to a remote apparatus, wherein said computer executable commands represents said data queries related to said pharmaceutical drug developed by a pharmaceutical drug manufacturer, and wherein said remote apparatus is operatively connected with a monitoring device through a device jack;

executing said computer executable commands at said remote apparatus to cause communication of at least one of said data queries to said individual;

receiving responses to said at least one of the communicated data queries from said individual;

receiving measurements from said monitoring device;

transmitting the received responses to a host system;

storing the transmitted responses and responses of said individual at said host system; and

generating a report to be sent back to said remote apparatus.

16.   (Original) The method of claim 15, further comprising audibly communicating said at least one of said data queries to said individual.

17.   (Original) The method of claim 15, further comprising audibly transmitting said received responses to said host system.

18.   (Original) The method of claim 15, further comprising transmitting said received responses to said host system through the Internet.

19.   (Original) The method of claim 15, wherein said responses comprise any of audible

responses, data entry responses, and direct responses.

20.   (Previously Presented) The method of claim 15, wherein said remote apparatus monitors any of blood glucose, respiratory flow, blood pressure, weight, and pulse rate of said individual.

21.   (Previously Presented) The method of claim 15, wherein said remote apparatus monitors any of an efficacy, side effects, and quality of life impact of said pharmaceutical drug on said individual.

I.   Status of the Application

With this amendment, claims 1-21 are currently pending in this application. Claims 1-21 stand rejected based on prior art and other statutory grounds. Claims 1, 9, and 15 have been amended. No claims have been added herein. In view of the foregoing discussion, the Examiner is respectfully requested to reconsider and withdraw the rejections.

II.   The 35 U.S.C. §103(a) Rejections

Claims 1-21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Iliff (U.S. Patent Publication No. 2008/0051638), in view of Policastro et al. (U.S. Patent No. 5,012,411), hereinafter referred to as "Policastro", and further in view of Pross et al. (U.S. Patent No. 5,343,869), hereinafter referred to as "Pross". In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw these rejections.

Iliff teaches a system and method for providing computerized, knowledge-based medical diagnostic and treatment advice. The medical advice is provided to the general public over networks, such as a telephone network or a computer network. The invention also includes a stand-alone embodiment that may utilize occasional connectivity to a central computer by use of a network, such as the Internet. New authoring languages, interactive voice response and speech recognition are used to enable expert and general practitioner knowledge to be encoded for access by the public. "Meta" functions for time-density analysis of a number of factors regarding the number of medical complaints per unit of time are an integral part of the system. A re-enter feature monitors the user's changing condition over time. A symptom severity analysis helps to respond to the changing conditions. System sensitivity factors may be changed

at a global level or other levels to adjust the system advice as necessary.

Policastro teaches a portable, self-contained, microprocessor controlled apparatus for monitoring, storing and transmitting detected physiological information, including an input section for sequentially receiving analog signals corresponding to heart activity for as many as twelve different cardiac sensors. An input section is provided for receiving analog electrical signals corresponding to blood pressure from at least one sensor. An analog to digital converter is provided for converting the received analog signals to a series of digital pulses at a predetermined sampling rate and for receiving and storing the digital pulses in predetermined memory locations. A control section is provided for recalling the stored digital pulses from the memory and for receiving the recalled digital pulses and for transmitting them to a remote location over a communications system. In the preferred embodiment, the input section is for receiving analog signals corresponding to cardiac conductivity, brainwave activity, blood pressure, blood flow and other ultrasonic cardiovascular and intracranial data. The latter signals are also converted to digital form for storage and later recall and transmission to a remote location.

Pross teaches a portable hand-held monitor (1) for monitoring vital signs is connected, via a single connector (7), with a cable (9). This cable ends up in a combiner (10) which, in turn, receives plugs (12a to 12d) leading, via cables (11a to 11d), to single sensors or transducers applied to a patient. Portable hand-held monitor (1) comprises a display (3) and internal memory means, in order to store recorded vital signs and to transmit them to a remote computer later on. As only a single cable (9) is required for connection with combiner (10), patient monitoring becomes quite easy if the combiner (10), cable (9) and the associated sensors and interconnection cables are left at or near the patient. In this case, a plug (8) connected with cable (9) has simply

to be inserted into connector (7), in order to start data acquisition. The same simple approach may be used to monitor the next patient, and so on.

Regarding claim 1, the Office Action states that Iliff discloses "a remote hand-held apparatus that receives one or more computer executable commands from said server over said communications channel and comprising at least one device jack that directly connects the remote hand-held apparatus with a monitoring device, wherein said computer executable commands represent data queries related to said pharmaceutical drug developed by a pharmaceutical drug manufacturer." The Applicant respectfully disagrees.

Applicant respectfully submits that the amended claim 1 claims "a remote interface device that generates data queries to be answered by the individual", which is supported by the Abstract section of the specification, and which Iliff completely fails to teach or suggest as Iliff merely discloses a script generator in Fig. 28. Further, it is respectfully submitted that the cited portion (Para [0622]-[0633]) of Iliff merely discloses that a computer is present at a patient location for interaction and MDATA system uses part of storage and processor of patient's computer, wherein the patient computer is used for accessing HTML data from MDATA computer, responding to queries accessed from the MDATA computer, storing MDATA, and printing patient medical reports. Iliff merely discloses accessing, processing, responding and storing queries related to the patient in the patient's computer. Iliff, in the complete specification merely discloses executing queries, but completely fails to teach or suggest a server that generates one or more computer executable commands based on data queries that are generated by a remote interface. On the other hand, the Applicant claims a remote handheld apparatus that receives one or more computer executable commands from the server, wherein the computer executable commands are generated based on data queries that are generated and assigned by a

remote interface device, and wherein the queries relate to medical pharmaceutical drugs developed by a drug manufacturer. Iliff completely fails to teach or suggest generating and assigning of data queries by a remote interface device to a server, but merely discloses executing of queries.

Further, the Office Action states that Iliff discloses "wherein said remote hand-held apparatus further (i) receives responses to said at least one of said data queries from said individual, and (ii) transmits said responses to said server." The Applicant respectfully disagrees.

It is respectfully submitted that all arguments made above are applicable. The cited portion (Fig. 28 and Para [0680]) of Iliff merely discloses data exchange and execution between patient computer and server, wherein if script engine executes script at the patient computer, MDATA system passes script to the gateway process for transfer of script to the patient computer and MDATA system utilizes script to transfer queries to the user, generating responses to a user input and to generate results. MDATA system disclosed by Iliff merely generates queries, receiving responses for the queries from the user and transferring the responses to the server, but completely fails to teach or suggest a remote interface device that generates and assigns data queries to the server, wherein the server then further generates computer executable commands based on the assigned data queries, which are answered by the user. Iliff, in the complete specification, completely fails to teach or suggest assigning of queries by the remote interface device to the server. On the other hand, the Applicant claims that the remote hand-held device apparatus receives responses for one or more queries from the user, wherein the queries are assigned by the remote interface device and transmits the responses to the server.

Further, the Office states that Iliff discloses "wherein said remote hand-held apparatus further (i) receives measurements from said monitoring device, and (ii) transmits said measurements to said server." The Applicant respectfully disagrees.

It is respectfully submitted that all arguments made above are applicable. The cited portion of Iliff merely discloses transfer of MDATA from a MDATA computer to a patient computer, executing script at the patient computer, responding and transferring the queries, storing responses, reports and patient medical data and saving session data for later uses, but completely fails to teach or suggest a remote hand-held apparatus receiving measurements from a monitoring device and transmitting measurements to a server. On the other hand, the Applicant claims that the remote hand-held device receives measurements from the measurement device regarding a patient and transmits the data to the server.

Further, the Office Action states that Policastro discloses "a portable apparatus for monitoring, storing and transmitting detected physiological information, wherein the remote apparatus is hand-held apparatus and comprising an input that receives input from monitoring device" The Applicant respectfully disagrees.

It is respectfully submitted that the cited portion of Policastro merely discloses an apparatus 10 for monitoring, storing and transmitting physiological data of a user, wherein the apparatus is small, portable and can record various physiological information of the user. The portable device disclosed by Policastro contains the physiological data measuring units such as ECG, EEG, blood pressure, heart rate information unit and other information units within itself. Further, Policastro merely discloses that an in-built circuitry that allows two-way communication between the portable device and a server, wherein a person handling the device, such as patient, nurse, paramedic, or the like will record the physiological data to the server or to a physician

directly for monitoring the data. The portable device disclosed by Policastro completely fails to teach or suggest a hand-held device or portable device receiving physiological data input from a monitoring device through an input, wherein the monitoring device is external to the hand-held device. On the other hand, the Applicant claims a portable device, which monitors, stores and transmits physiological data, wherein the portable device receives physiological input from a monitoring device.

Regarding claim 6, the Office Action states that Policastro discloses "further comprising a monitoring device monitors any of blood glucose, respiratory, flow, blood pressure, weigh, pulse, and rate of said individual." The Applicant respectfully disagrees.

It is respectfully submitted that the arguments made above are applicable. The cited portion of Policastro merely discloses receiving, storing and transmitting of physiological data by a portable device, wherein the portable device includes in-built physiological data measuring units such as ECG, EEG, weigh, blood pressure, heart information and other information units and stores the physiological data in a storage unit and transmits to a server, but completely fails to teach or suggest a portable device receiving physiological input data from a separate and distinct measuring unit. On the other hand, the Applicant claims that the remote apparatus receives physiological input data such as blood pressure, glucose, respiratory, flow, weigh, pulse and rate of said individual from a measuring device. The portable device disclosed by Policastro is completely different from the portable device claimed by the Applicant, wherein the portable device of Policastro comprises of physiological data measuring units within itself when compared to the portable device claimed by the Applicant, which receives physiological data from a separate measuring device.

Regarding claims 9-21, all arguments made above for claims 1-8 are applicable.

As discussed above, the proposed combination of the references does not include all of the above claim limitations therefore, *prima facie* obviousness has not been established. Mere conclusory statements cannot sustain rejections on obviousness; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness (MPEP 2141 III). However, the proposed combination of references does not have all the elements for the presently claimed invention as amended. The Office Action does not explain why the elements missing from the proposed combination would have been obvious to one ordinary skill in art. Therefore, the Office Action does not support the rejection under 35 U.S.C. §103 with a clear articulation of the reason(s) why the claimed invention would have been obvious in view of the cited references.

For any of these reasons, the aforementioned feature(s) of independent claim(s) 1, 9, and 15 cannot reasonably be said to be present in any of the asserted combinations. The failure of an asserted combination to teach or suggest each and every feature of a claim remains fatal to an obviousness rejection under 35 U.S.C. §103, despite any recent revision to the Manual of Patent Examining Procedure (MPEP). Section 2143.03 of the MPEP requires the "consideration" of every claim feature in an obviousness determination. To render claims 1-21 unpatentable, however, the Office must do more than merely "consider" each and every feature for this claim. Instead, the asserted combination of the cited prior art must also teach or suggest *each and every claim feature*. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (emphasis added) (to establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art).

In view of the foregoing, the Applicants respectfully submit that the features defined by independent claims 1, 9, and 15 contain patentable subject matter and as such, claims 1, 9, and

15 are patentable over the prior art of record. Further, dependent claims 2-8, 10-14, and 16-21 are similarly patentable not only by virtue of their dependency from patentable independent claims, respectively, but also by virtue of the additional features of the invention they define. Moreover, the Applicants note that all claims are properly supported in the specification and accompanying drawings, and no new matter is being added to the application.

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections.

III.   **Formal Matters and Conclusion**

In view of the foregoing, the Applicant submits that claims 1-21, all the claims presently pending in the application, are patentably distinct from the prior art of record and are in

condition for allowance. The Examiner is respectfully requested to pass the above application to issue at the earliest possible time. Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary. Please charge any deficiencies and credit any overpayments to Attorney's Deposit Account Number 50-3831.

Respectfully submitted,

Dated: <u>November 9, 2011</u>

<u>/Mohammad S. Rahman/</u>
Mohammad S. Rahman
Registration No. 43,029

Rahman LLC
10025 Governor Warfield Parkway, Suite 110
Columbia, MD 21044
Voice: (443) 283-7000
Fax: (443) 283-8430
Customer No. 60683