BL O/233/06

16 August 2006

PATENTS ACT 1977

APPLICANTS Robert Momich and Michael E Infuso

ISSUE Whether patent application number GB 0415793.9 complies with sections 1(1)(b) and 1(2)

HEARING OFFICER R C Kennell

DECISION

Background

1 The above patent application results from the entry into the national phase for the UK of international application no. PCT/CA02/01986 which was filed on 23 December 2002 and claimed a priority date of 21 December 2001. The international application was published under serial no. WO 2003/056491 on 10 July 2003 and subsequently reprinted under serial no. GB 2400219 A by the UK Patent Office.

2 Although the claims have been amended in the course of prosecution, the applicants have failed to overcome the examiner's objections that the claims in their latest form lack inventive step as required by section 1(1)(b) and that it was not possible to identify any advance made by the invention which was not excluded under section 1(2), having regard to the test propounded by Peter Prescott QC, sitting as a Deputy Judge of the High Court, in *CFPH LLC's Application* [2005] EWHC 1589 (Pat), [2006] RPC 5 which is now applied by the Patent Office (see the notice "Examining for patentability" available on the Office's website at http://www.patent.gov.uk/patent/notices/practice/examforpat.htm). With the applicants' agreement I am deciding the matter on the basis of the papers on file.

The application and amendments thereto

3 The application relates to an electronic system, described as a "clinical trial subject prompter", for data collection in clinical trials of new drugs which

prompts the subject to take the drug at an appropriate time ("medical compliance") and also generates a diary form for the subject to complete. The diary form enables the subject to monitor his or her reactions to the drug and self-medication history, this data being critical to the success of a trial. The system requires no training on the part of the subject and can be hosted on existing portable devices such as cell phones, hand held computers and personal organisers. As the applicants point out, a fully electronic system of this nature improves the accuracy and richness of the data which is collected, and makes it easier for researchers to build up a full picture of the effects of the new medication.

4 The examiner considered that the claims as originally filed, which were in terms of "a method for use in association with clinical trials for a medication" did not relate to a new and non-obvious advance in a field not excluded under section 1(2). The applicants saw the advance as lying in the realisation that a portable computerised device could combine both the medication compliance function with the display of diary forms for completion by the subject, there being direct interaction between the two features in that failure to complete the diary could be used to prevent further medication prompts being given. The examiner was prepared to accept that a claim to a device in these terms (if new and inventive) should not be excluded under section 1(2).

5 Accordingly examination proceeded on the basis of the following amended claim 1, filed with the applicants' letter of 25 April 2006:

> "An interactive reminder device to prompt a user to take medication stored in a package in a timely manner in accordance with a medication regime, the device being personal to the user and comprising means for storing a next take time for the medication and means for prompting when the next take time is due, the device:
>
> (a) storing a unique identifier;
>
> (b) being able to write that unique identifier to an integrated circuit chip on the medication package if no such unique identifier is already present on the integrate circuit; and
>
> (c) being able to read an identifier from an integrated circuit chip on a medication package and being able to compare it to the stored unique identifier and to confirm to the user that the package contains medication for that user only if there is a match;
>
> characterized in that the device displays a subject diary form to capture data relevant to a clinical trial, stores information input by the patient into the device in response to the form and halts prompting if the form is not properly completed.";

the appendant claims as amended are recited in the Appendix to this decision. Following search (none at that point yet having been carried out) the examiner raised the objections mentioned at paragraph 2 above in respect of all the claims.

6 The applicants have asked me to consider the above claim and also an alternative in which the characterising part is replaced by the following:

> " characterized in that the device stores a pointer to a remote site on a network, the pointer being used to retrieve one or more of the following: (a) a subject diary form to capture data relevant to a clinical trial; (b) compliance management parameters for the medication."

Arguments

7 The examiner has cited the following documents, taken in combination, to demonstrate that all the claims lack inventive step:

1 WO 01/08106 A2 (Momich and Infuso)
2 US 5 642 731 (Kehr)
3 US 6 148 815 (Wolf)
4 EP 1 087 322 (RXVP Inc)
5 EP 1 034 734 (Brown)
6 US 6075 755 (Zarchan)
7 US 5 672 154 (Sillen et al)
8 US 6 294 999 B1 (Yarin et al)
9 US 4803 625 (Fu et al)
10 US 4 837 719 (McIntosh et al);

all of them relate to the monitoring the compliance of patients with medication regimes. As I understand it the essence of his argument is that

- most of the features which distinguish the invention from the medication package and interactive reminder device disclosed in the applicant' earlier application relate to scheduling and administering a record keeping process and were disclosed in the above documents;

- stopping further compliance monitoring in response to a failure to complete the diary form is not inventive because it would be standard practice for a health professional to stop or alter the medication regime according to patient health data or deviation from the prescribed regime, the automation of such a procedure being implicit in the above documents; and

- the sensing of other medical data (claims 18 and 19) and authentication by PIN number or biometric data (claims 23 and 24) are well known.

8 Following the *CFPH* test, the examiner considers that in the light of the above the only advance the invention might make lies in the customisation of a diary keeping method for use with a known medication management system. This he considers to lie in areas excluded under section 1(2), especially computer programming but possibly also business methods and

mental acts.

9 Responding to the examiner, the applicants believe the argument that it is standard practice for a health professional to stop or alter the medication regime according to health data is relevant only for approved drugs. They point out that in clinical trials the drug is by definition not approved and patient health data is not known: the problem which the invention solves is to design a medication prompting device which will enable subject diary information to be captured in a manner that is reliable and hence statistically valid. They further explain that to achieve this the device must do more than just prompt the user to take medication: it must also enforce completion of the subject diary forms, and it does this by halting prompting if they are not completed.

10 The applicants believe that there is nothing analogous in the prior art to the cessation of prompting if the patient fails to give feedback as to their health and nothing which would lead the skilled person as a matter of course to modify existing prompting devices in this way. They suggest that in the normal hospital context a nurse would not stop reminding a person to take medication just because the patient declined to say how he or she was feeling.

Analysis

11 However, I do not think this is the starting point which I should take on the issue of inventive step. Rather, I need to look at the background against which the invention has been made as explained in the application as published, particularly at page 1 line 13 - page 2 line 31 and page 5 line 17 - page 6 line 18.

12 From these passages it is clear that researchers conducting clinical trials have been struggling to cope with paper based systems. As the specification states, until very recently the “mountains” of diary and case report form data have been collected and recorded only on paper during visits of the subjects to research co-ordination centres to obtain refills of the trial medication. Such paper reports rely heavily on the subject’s memory. The data which they produce is frequently incomplete and unreliable, and the task of organising it into a form suitable for submission to approval bodies is formidable. The specification also explains that, whilst clinical trial data collection poses problems additional to those associated with personal medical use, compliance with medication directions is as much a concern of those conducting medication trials as it is for the monitoring of use of approved drugs. The specification explains that in consequence a transition to electronic data capture is underway and that this entails a recognition that the processes used to conduct trials will need to be re-engineered.

13 Against this background I believe that the skilled person seeking to improve the process of conducting clinical trials would look at the teachings of documents which are directed to the electronic monitoring of compliance with medication instructions and whether this might be combined with feedback from the subject, irrespective of whether the documents related to clinical trials of unapproved drugs or the personal use of prescribed approved drugs. In my view, therefore the skilled person would have considered all the documents cited by the examiner.

Claim 1

14 It appears to me, and I do not understand it to be disputed, that document 1, which is the applicants' earlier application, discloses features in the "pre-characterising" part of claim 1, namely a device which stores a next take time and prompts the user when it is due, and which reads an identifier from an integrated circuit chip on a medication package and compares it with a stored unique identifier. The applicants' argument is that the addition to this of the characterising features of claim 1 is not something which the skilled man would be led as a matter of course to do.

15 These features comprise (a) display of a "subject diary form" to capture data relevant to the trial, (b) storage of information input by the patient in response to the form, and (c) halting processing if the form is not properly completed. The term "subject diary form" is not defined but at page 6 lines 24-27 it is stated that "there is an additional step to prompt the subject to qualitative or subjective and quantitative or parametric questions designed by the trial sponsor and clinical investigator to produce an electronic patient diary". Figure 6 shows a sample form as a single document, but it is stated at page 9 lines 8-9 that the text forms may be displayed which have menu choices and/or text entry fields, and at page 15 lines 7-10 that the forms may vary greatly depending on the needs of the research coordinators and the platform that is used. In the light of this I would regard the term "form" as embracing the sequential presentation of questions to the subject for completion, as well as in the form of a single "sheet". With that in mind, and despite the applicants' contentions, it seems to me that features (a) and (b) are disclosed in a number of the cited documents.

16 Thus, document 2 is specifically directed (see col 2 lines 18-27) to gathering clinical information about a patient whilst simultaneously gathering medical compliance data, at times which do not correspond to visits to the doctor and at multiple points throughout the drug delivery cycle, in order to provide a more accurate picture of the effect of different drug levels and combinations of drugs. The possibility of using such information as part of a clinical trials study, amongst other purposes, is mentioned at col 22 lines 32-41. The system is based on a programmable microprocessor chip which accepts

various user inputs and performs the necessary logic. At col 3 line 48 - col 4 line 47 are disclosed various types of information which the patient might be prompted to enter, such as self-diagnosis of any new illnesses which might be developing, reasons for failing to take a drug at a scheduled time or for taking a drug at an unscheduled time, attitudes towards illness and treatment, and lifestyle factors. Typically this information is input by means of a programmable touch-screen which displays questions and information.

17 Document 5 at paragraphs [0033] to [0047] discloses a system in which a remote monitoring centre downloads a medical schedule to a base station (which is preferably at the patient's home) generally by telephony. The base station communicates the schedule, eg by radio wave transmission, to a portable medical device such as a pill bottle which alerts the patient when medication should be taken or when a medical measurement should be taken. For the better motivation of the patient the system provides for interactive reporting of medical information with a facility for the patient to reply to questions from a clinician or to ask questions, preferably by means of a contact button which activates an e-mail screen that can generate text, voice or video formats for replying.

18 Document 6 discloses a watch which is programmable with a medication regime via an infrared or other electronic data transfer link to a healthcare provider's computer system. The watch gives an alarm when medication is taken or a healthcare procedure is to be performed and allows the patient to record medical events into the watch's memory so that compliance and patient history can be reviewed. It also has a mode (see col 13 line 64 - col 15 line 10) in which the watch can be programmed to lead the patient through a series of questions and responses, and may prompt the patient for specific information or to respond to questions by selecting from a set of choices.

19 Document 7 is directed to the problem of controlling individual medication for diseases and conditions such as Parkinson's disease, epilepsy and abnormal blood pressures, where treatment may involve several medicines whose precise effects are not fully known and where the patient's health may be affected by a plurality of external factors. It discloses an "expert" system, conveniently implemented in a portable wallet-size computer, in which a reminder function is combined with a recording function which allows the patient to confirm that medication has been taken, to respond to questions about his current state of health put to him by the computer and to record other relevant events as they occur. Inductive data analysis spots the relationships between various events and symptoms and establishes medication rules which can be adapted to changes in the patient's state of health as new information is recorded.

20 Document 9 discloses (see particularly col 9 line 59 - col 12 line 24) a

personal health monitor which is coupled to a central unit and includes a computer which prompts a patient to take prescribed medication at prescribed times, to use sensors in the monitor to measure prescribed health parameters and to supply answers to selected questions. In the event of a discrepancy between measured and expected values the computer can be programmed to collect additional information to enable personnel at the central unit to interpret the composite data.

21 In the light of these documents I am of the view that the skilled man would regard the generation of a form on which the subject can record additional data as a routine "add-on" not requiring inventive effort, irrespective of whether the form is for the benefit of a clinician prescribing personal medicine or a researcher conducting a clinical trial,. As I have explained above, I do not think the skilled man would draw any distinction between the two situations when considering the prior art documents, and this is borne out by the references to clinical trials in document 2 identified above, and also in document 3 (see col 1 line 46 - col 2 line 43). I would also observe that the system for determining the appropriate medication regime for a patient in the circumstances described in document 7 seems to have much in common with a clinical trial.

22 Using the well-known *Windsurfing*[1] test for inventive step, the difference between the invention as claimed in claim 1 and the matter which appears from the citations to be known or used therefore lies in step (c), the halting of further reminders if the subject fails to complete the diary form. I have outlined above the arguments of the examiner and the applicants, and having considered them both I am in agreement with the examiner.

23 I do not think there can be any dispute that a health professional would as a matter of course step in to stop or alter the medication regime according to patient health data or deviation from the prescribed regime, and I cannot see that it would be anything other than a routine matter to introduce such an "override" into an electronic monitoring system if required. The question though is whether the skilled man would be led as a matter of course to introduce such a feature and here I am not persuaded by the applicants' arguments which are based on a perceived difference between a clinical trial and the monitoring of approved drugs.

24 As explained above, clinical researchers have been aware of the desirability of re-engineering the paper process so as to ensure greater reliability in completing diary forms in an electronic system, and I do not therefore think it would take any great leap of the imagination to introduce a feature which stopped further prompting if the subject did not appear to be playing ball. Nor am I convinced by that the applicants' suggestion that there is a fundamental

[1] Windsurfing International Inc v Tabur Marine (Great Britain Ltd) [1985] RPC 59

distinction between the clinical trials and medical monitoring of patients because in the latter context a nurse would not stop reminding a person to take medication just because the patient kept quiet. On the contrary, I think there might well be situations where a failure to respond, say where there was an element of doubt about what needed to be prescribed or in what amount, would be serious enough for a nurse to stop giving reminders and seek further advice from a doctor.

25 Finally I would observe that despite the applicants' arguments, no great significance is attached to this feature in the application as originally filed. The possibility of halting the medication prompting in the event of failure to complete a question is merely mentioned at page 11 lines 19-23 as a possibility provided it is desired by the investigators, and it is not shown in any of the specific flow charts illustrating the invention.

26 In my view therefore feature (c) is not inventive and claim 1 in consequence lacks inventive step.

Claims 2-26

27 On whether the remaining claims lack inventive step, the examiner considers that these are for the most part features relating to a record-keeping process which are disclosed in the cited documents, but has not stated which documents or parts thereof are relevant to which claims. However, I do not think it is necessary for me to undertake an exhaustive analysis of the citations to determine this matter. Except for the proposed alternative claim, the applicants have not queried the examiner's conclusion. Further, having carefully read the applicants' specification, it seems to me that once you have the device of claim 1 all the features of the remaining claims either relate to features which are disclosed in the applicants' earlier specification (document 1) in relation to the compliance aspects, or are conventional options which the skilled man would incorporate into the device of claim 1. I can find nothing in the description to suggest that any of these features are inventive in their own right.

28 This includes the features of claims 18/19 relating to the sensing of medical data, and claims 23/24 relating to the use of a PIN or biometric data which the examiner has specifically mentioned. As the examiner points out the sensing of medical data is mentioned in some of the cited documents, eg documents 5, 8, 9 and 10.

Alternative claim

29 The applicants have proposed an alternative claim relying on the use of a pointer to a remote site on a network to retrieve a subject diary form or compliance parameters. They state no reason why this feature is inventive.

In view of my finding that the generation of the diary form would be a routine feature, and having regard to the way in which the use of a pointer is described at page 10 lines 10-13 and page 10 line 29 - page 11 line 2 as something which would be appreciated by those skilled in the art, this would seem to be a conventional feature which would not make the proposed claim inventive.

The advance made by the invention

30 The examiner has stated that the only advance he can identify within the specification is the customisation of a diary keeping method for use with a known medication system, but any advance in this area would lie within areas excluded under section 1(2). I am not clear which parts of the specification he has in mind, but having read it carefully I cannot find anything in the specification which would be new and not obvious in relation to the prior art and which would constitute a patentable advance.

Conclusion

31 Although I have reached my conclusion by a slightly different route from the examiner, I agree with him that all the claims lack inventive step and I cannot see any patentable advance which the invention makes. I therefore refuse the application in accordance with section 18(3) of the Act.

Appeal

32 Under the Practice Direction to Part 52 of the Civil Procedure Rules, any appeal must be lodged within 28 days - although I observe that the period prescribed by rule 34 of the Patents Rules 1995, if retrospectively extended under rule 110(3), will expire on 21 August 2006, before the 28 day appeal period expires.

R C KENNELL
Deputy Director acting for the Comptroller

APPENDIX TO DECISION O//06

Dependent claims 2 -26 as amended

2. The device as claimed in claim 1 operable to display the subject diary form at a time proximate to a time at which the next take time is prompted.

3. The device as claimed in any one of claims 1 and 2 operable to display the subject diary form at predetermined times.

4. The device as claimed in any one of claims 1 to 3 operable to display the subject diary form in response to a request.

5. The device as claimed in any one of claims 1 to 4 operable to receive an indicator regarding taking the medication prior to storing the time on a clock as a take time.

6. The device as claimed in any one of claim 1 to 5 operable to calculate a next take window and identify if the present time is within the next take window.

7. The device as claimed in any one of claim 1 to 6 operable to calculate a deferred next take time and prompt the user at the deferred next take time.

8. The device as claimed in any one of claim 1 to 7 operable to read and display further information stored on one of the device and a smart memory associated with the device.

9. The device as claimed in any one of claim 1 to 8 operable to:
determine if a next form field is null; if yes then determining if a next take field is null; if yes then exiting;
if the next form field is not null then determine if the next from field date and time correspond to the clock date and time; if yes then display the patient diary form; if no then return to beginning; and
if the next take field is not null then determine if the next take field date and time correspond to the clock date and time; if yes then prompt; if no then return to the beginning.

10. The device as claimed in any one of claim 1 to 9 wherein the take time and the patient information is stored on one of the smart memory associated with the medication and a smart card.

11. The device as claimed in any one of claim 1 to 10 wherein the take time and the patient information is stored on both the smart memory associated with the medication and a smart card.

12. The device as claimed in any one of claim 1 to 11 operable to load the subject diary form from one of a subject smart card, the smart memory associated with the medication, a remote site via a pointer on a subject smart card and a remote site via a pointer on the smart memory associated with the medication.

13. The device as claimed in any one of claims 1 to 12 operable to read and display further information stored on the smart memory on the device.

14. The device as claimed in any one of claims 1 to 13 wherein the take time and the patient information is stored on one of the smart memory associated with the medication and a smart card.

15. The device as claimed in any one of claims 1 to 14 wherein the take time and the patient information is stored on both the smart memory associated with the medication and a smart card.

16. The device as claimed in any one of claims 1 to 15 operable to load the subject diary form from one of a subject smart card, the smart memory associated with the medication, a remote site via a pointer on a subject smart card and a remote site via a pointer on the smart memory associated with the medication.

17. The device as claimed in any one of claims 1 to 16 operable to receive an indicator regarding taking the medication prior to the step of storing the time on a clock as a take time.

18. The device as claimed in any one of claims 1 to 17 operable to sense and store medical data.

19. The device as claimed in claim 18 wherein the medical data is chosen from the group consisting of temperature, heart rate, blood pressure, blood chemistry and a combination thereof.

20. The device as claimed in any one of claims 18 and 19 wherein the sensing and storing of medical data is conducted at a time proximate to a time at which the next take time is prompted.

21. The device as claimed in any one of claims 18 and 19 wherein the sensing and storing of medical data is at predetermined times.

22. The device as claimed in any one of claims 18 and 19 wherein the sensing and storing of medical data is responsive to a request.

23. The device as claimed in any one of claims 1 to 22 wherein a unique personal identification number is present and the device receives a personal identification number and determines if the personal identification number is the unique personal identification number and, if not, exits.

24. The device as claimed in any one of claims 1 to 23 wherein a unique personal biometric data is present and the device is operable to receive a personal biometric data and determines if the personal biometric data is the unique personal biometric data and, if not, exits.

25. The device as claimed in any one of claims 1 to 24 wherein the setup routine

includes the steps of:

writing a writing (*sic*) the unique identifier on to the smart memory;
determining if taking now, if no then exiting, if yes then:

receiving information regarding a method of calculating a next take time;

calculating the next take time;
storing a next take time;

prompting at the next take time;

storing the time on the clock as a take time;
displaying a subject diary form; and

storing subject information in regard to the subject diary form.

26. The device as claimed in any one of claim 1 to 25, being an electronic personal organizer, a cell phone, a personal digital assistant, or a hand held computer.

R C KENNELL