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LONG, FONYA M

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOHN W. HOURIET, JR. and JIANBO PENG

Appeal 2014-006860
Application 12/692,897
Technology Center 3600

Before BIBHU R. MOHANTY, NINA L. MEDLOCK, and
TARA L. HUTCHINGS, *Administrative Patent Judges*.

MOHANTY, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

The Appellants seek our review under 35 U.S.C. § 134 of the final rejection of claims 1–36, which are all the claims pending in the application. We have jurisdiction under 35 U.S.C. § 6(b).

SUMMARY OF THE DECISION

We REVERSE.

THE INVENTION

The Appellants' claimed invention is directed to managing a database lock for a clinical trial study (Spec., page 3, lines 8–9). Claim 1, reproduced below, is representative of the subject matter on appeal.

1. An automated method of generating summary data regarding task items that must occur to achieve a database lock for a clinical trial study that is performed based on a previously defined clinical trial protocol, the clinical trial study being managed using (i) a processor, and (ii) a database in communication with the processor, the database including clinical trial data and the status of the data for a plurality of patients participating in the clinical trial study, the method comprising:

(a) defining, using the processor, at least one clinical database lock criterion for the study from at least a plurality of user-selected subsets of the clinical trial data, wherein the clinical database lock criterion is defined using the previously defined clinical trial protocol;

(b) inputting into the processor:

(i) the at least one clinical database lock criterion for the study, and

(ii) the clinical trial data and the status of the data, as retrieved from the database, for the plurality of patients participating in the clinical trial study as defined by the clinical database lock criteria; and

(c) automatically and programmatically generating, using the processor, summary data regarding task items that must occur to achieve the database lock as defined by the at least one clinical database lock criterion, using the clinical trial data and the status of the data, wherein different summary data will be generated for different clinical database lock criteria.

THE REJECTIONS

The following rejections are before us for review:

1. Claims 1–14, 16, 19–32, and 34 are rejected under 35 U.S.C. § 103(a) as unpatentable over Briegs et al. (US 7,054,823 B1, issued May 30, 2006) (“Briegs”).
2. Claims 15 and 33 are rejected under 35 U.S.C. § 103(a) as unpatentable over Briegs and Shah (US 2004/0093240 A1, issued May 13, 2004).
3. Claims 17 and 35 are rejected under 35 U.S.C. § 103(a) as unpatentable over Briegs and OmniComm’s TrialMaster (TrialMaster brochure, OmniComm Systems, Inc. (2007)).
4. Claims 18 and 36 are rejected under 35 U.S.C. § 103(a) as unpatentable over Briegs and Rosenberg (US 2008/0270181 A1, published Oct. 30, 2008).

FINDINGS OF FACT

We have determined that the findings of fact in the Analysis section below are supported at least by a preponderance of the evidence.¹

ANALYSIS

The Appellants argue that the rejection of claim 1 is improper because the cited prior art fails to disclose elements of claim limitation (a) identified above (App. Br. 9–13; Reply Br. 2–5).

In contrast, the Examiner has determined that the cited claim limitation would have been obvious in view of the following portions of

¹ See *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Patent Office).

Briegs: the Abstract, col. 2:11–14, col. 2:35–43, col. 9:39–40, col. 24:12–19, col. 25:11–12, and col. 31:24–34 (Ans. 2, 3, 9).

We agree with the Appellants. Claim limitation (a) requires:

(a) *defining, using the processor, at least one clinical database lock criterion for the study from at least a plurality of user-selected subsets of the clinical trial data, wherein the clinical database lock criterion is defined using the previously defined clinical trial protocol.*

(Claim 1, emphasis added). Initially we note the claimed distinction between a “clinical trial *study*” and a “*previously defined clinical trial protocol*” that is set forth in both the preamble and body of the claim. The cited claim limitation requires “defining . . . *at least one clinical database lock criterion for the study from at least a plurality of user-selected subsets of the clinical trial data . . . defined using the previously defined clinical trial protocol.*” Here, the above citations to Briegs do disclose disparate elements of the claim limitation, but not in the specific manner claimed. For example, the Abstract does disclose designing and monitoring clinical trials and that protocols of prior clinical trials are stored in a database. However, the Abstract fails to disclose a “*database lock criterion for the study from at least a plurality of user-selected subsets of the clinical trial data.*” Briegs at col. 15:10–22 does disclose changing the status from “Concept to Finalize” (locking from further change), but this also fails to disclose a “*database lock criterion for the study from at least a plurality of user-selected subsets of the clinical trial data.*” Even assuming arguendo that the cited portions of Briegs describe the discrete elements of the argued claim limitation, the rejection nonetheless lacks the requirements to show obviousness. Here, there is no articulated reasoning with rational underpinnings for modifying

the cited portions of Briegs to meet the argued claim limitation in the specific manner claimed without impermissible hindsight. For these reasons, the rejections of claim 1 and its dependent claims are not sustained.

The remaining independent claims contain limitations similar to the one discussed above, and the rejections of these claims and their dependent claims are not sustained for these same reasons.

CONCLUSIONS OF LAW

We conclude that Appellants have shown that the Examiner erred in rejecting the claims as listed in the Rejections section above.

DECISION

The Examiner's rejections of claims 1–36 are reversed.

REVERSED