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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RYUICHI TOHMA

Appeal 2014-003874¹
Application 10/703,935²
Technology Center 3600

Before JOSEPH A. FISCHETTI, PHILIP J. HOFFMANN, and
MATTHEW S. MEYERS, *Administrative Patent Judges*.

MEYERS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant appeals under 35 U.S.C. § 134(a) from the Examiner's final rejection of claims 52–81. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ Our decision references Appellant's Appeal Brief ("Appeal Br.," filed October 11, 2013) and Reply Brief ("Reply Br.," filed January 21, 2014), the Examiner's Answer ("Ans.," mailed November 20, 2013), and Final Office Action ("Final Act.," mailed September 12, 2012).

² Appellant identifies Sysmex Corporation as the real party in interest (Appeal Br. 2).

CLAIMED INVENTION

Appellant's claimed invention relates generally "to clinical laboratory systems connecting computers and analyzers through a network for managing examination information relating to clinical examinations" (Spec. 2, ll. 6–9).

Claims 52, 62, and 72 are the independent claims on appeal. Claim 52, reproduced below with added bracketed notations, is illustrative of the subject matter on appeal:

52. A non-transitory storage medium that stores programs executable by at least one computer of a plurality of computers forming a clinical laboratory system to:

[a] create, in a database, an entry which comprises an identification of a patient, a type of analysis requested on a sample from the patient and an identification of analyzer capable of performing the requested type of analysis;

[b] each time a workflow for analyzing the sample advances to respective workflow points, which comprise at least some of (i) a point at which the sample is received, (ii) a point at which the sample is arrived, (iii) a point at which the required type of analysis is completed on the sample, (iv) a point at which a result of the analysis is verified, and (v) a point at which a report is sent regarding the result of the analysis, update the entry by adding to the entry a time stamp indicating a chronology of progress to a respective point;

[c] select entries in the database which meet at least one of a first set of screening conditions, which comprise (a) a condition for selecting all entries in the database, (b) a condition for selecting an entry in which a particular type of sample is analyzed and (c) a condition for selecting an entry in which a particular analyzer is used;

[d] extract entries from among the selected entries which meet at least one of a second sets of screening conditions comprising time conditions each for extracting an entry that does not advance to one of the workflow points within a

predetermined time expected to take to advance to the one workflow point; and

[e] prepare a notice for display for notifying the extracted entries, at least some of which are each marked with an elapsed time measured from the time stamp of one of preceding workflow points.

REJECTIONS

Claims 52–57, 61–67, 71–77, and 81 are rejected under 35 U.S.C. § 103(a) as unpatentable over Kahn (US 2003/0065669 A1, pub. Apr. 3, 2003) and Hendrickson (US 5,740,800, iss. Apr. 21, 1998).

Claims 58–60, 68–70, and 78–80 are rejected under 35 U.S.C. § 103(a) as unpatentable over Kahn, Hendrickson, and Dettinger (US 7,089,235 B2, iss. Aug. 8, 2006).

ANALYSIS

Independent claim 52 and dependent claim 53–61

We are persuaded by Appellant’s argument that the Examiner erred in rejecting independent claim 52 under 35 U.S.C. § 103(a) because Kahn, upon which the Examiner relies, fails to disclose or suggest limitation [d] of independent claim 52 which recites:

extract entries from among the selected entries which meet at least one of a second sets of screening conditions comprising time conditions each for extracting an entry that does not advance to one of the workflow points within a predetermined time expected to take to advance to the one workflow point.

(*See* Appeal Br. 23; *see also* Reply Br. 3).

The Examiner maintains that the rejection is proper, and cites paragraphs 147–149, 194–196, and 199, as well as Figures 34–38 and claims 1–13, of Kahn as disclosing the argued limitation (*see* Final Act. 4;

see also Ans. 6). However, we agree with Appellant that there is nothing in the cited portions that discloses or suggests the argued limitation.

Kahn is directed “to a system and method using medical informatics primarily to predict study progress timelines based on easily modifiable assumptions” (Kahn ¶ 2). More particularly, Kahn discloses

clinical trials are defined, managed and evaluated according to an overall end-to-end system solution which covers both the protocol design and the actual conduct of trials by clinical sites. A protocol designer chooses a meta-model and preliminary eligibility criteria list appropriate for the relevant disease category, and encodes the clinical trial protocol, including eligibility and patient workflow, into a machine-readable protocol database. This protocol database then drives most subsequent aspects of the trial.

(*Id.* ¶ 78; *see also id.* ¶¶ 147–148). Kahn further discloses that

[o]nce a patient is enrolled into a study, the protocol database indicates to the clinician exactly what tasks are to be performed at each patient visit. The workflow graph embedded in the protocol database advantageously also instructs the proper time for the clinician to obtain informed consent from a patient during the eligibility screening process, and when to perform future tasks, such as the acceptable date range for the next patient visit.

(*Id.* ¶ 79). Kahn discloses “[t]he use of a machine-readable protocol database to store most significant aspects of a clinical trial protocol enables the development of automated tools to analyze the protocol and provide timely information to the protocol designer and the sponsor” (*id.* ¶ 81).

Kahn still further discloses that

[o]nce these time indications are embedded into a machine-readable protocol database, a problem-solving method is used to automatically extract the time duration expected or predicted for a patient to traverse each separate phase of the protocol. Such durations are provided to a simulation engine, which automatically generates timeline forecasts of patient progress

through at least part of the workflow tasks prescribed by the protocol.

(*Id.* ¶ 82; *see also id.* ¶¶ 194–195). Kahn also discloses “[t]he ability to re-run the simulation quickly is also highly desirable for study sponsors keeping track of actual study progress” to “learn not only how far off the forecasted number of patients in each protocol phase are from the actual number at that point in time, but also how the difference will impact the study completion date” (*id.* ¶ 196).

The difficulty with the Examiner’s analysis, as Appellant points out, is that

[p]aragraphs 147–149 discuss development of criteria for selecting patients eligible for clinical trials and have nothing to do with claim limitation [d], which requires a second selection of already selected entries based on whether or not an entry has advanced to a point as scheduled. Paragraphs 194–196 discuss simulation of timeline which indicates an expected patient progress through a clinical trial and again have nothing to do with claim limitation [[d]].

(Appeal Br. 23). In this regard, we note the cited portions of Kahn relate to selecting a meta-model for a clinical trial protocol under development (Kahn ¶¶ 147–149) and to “the output of the simulation engine **3410** [which] indicates a timeline of expected patient progress through a clinical trial conducted according to a clinical trial protocol represented in a machine readable iCP database” (*id.* ¶ 194; *see also id.* ¶¶ 92, 195–196, 199; Figs. 34–38), but do not disclose or suggest “extracting an entry that does not advance to one of the workflow points within a predetermined time expected to take to advance to the one workflow point,” as limitation [d] of independent claim 52 requires.

Responding to Appellant's argument in the Response to Argument section of the Answer, the Examiner takes the position that

the cited prior art discloses the feature stating “. . . extracting the required information from the electronically stored iCP database and writing it to a file for subsequent importation into the simulation engine 3410, an Application Programming Interface (API) can be provided for the simulation engine 3410 to extract the information directly, as needed, from the iCP. In an embodiment, instead of extracting duration information from the iCP for the three coarse stages (screening, treatment[,] and follow-up).”

(Ans. 6 (citing Kahn ¶ 199)). However, as discussed above, the cited portion of Kahn is directed to timeline forecasting, i.e., “the output of the simulation engine **3410** indicates a timeline of expected patient progress through a clinical trial conducted according to a clinical trial protocol” (Kahn ¶ 194; *see also id.* ¶¶ 194–196, 199; Figs. 34–38). We fail to see, and the Examiner does not adequately explain, how Kahn's disclosure regarding timeline forecasting discloses or suggests “extracting an entry that does not advance to one of the workflow points within a predetermined time expected to take to advance to the one workflow point,” as called for by limitation [d] of independent claim 52. The Examiner does not rely on Hendrickson to address the argued limitation (*see* Final Act. 4).

In view of the foregoing, we do not sustain the Examiner's rejection of independent claim 52 under 35 U.S.C. § 103(a). For the same reasons, we also do not sustain the Examiner's rejections of claims 53–61, which depend therefrom.

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Independent claims 62 and 72, and dependent claims 63–71 and 73–81

Each of independent claims 62 and 72 includes a limitation similar to limitation [d] in independent claim 52, and is rejected based on the same rationale applied with respect to independent claim 52 (*see* Final Act. 6–7, 8–9). Thus, for the same reasons, we also do not sustain the Examiner’s rejection of independent claims 62 and 72 under 35 U.S.C. § 103(a). For the same reasons, we also do not sustain the Examiner’s rejections of claims 63–71 and 73–81, which depend therefrom.

DECISION

The Examiner’s rejections of claims 52–81 under 35 U.S.C. § 103(a) are reversed.

REVERSED