2016 Pat. App. LEXIS 2105

Patent Trial and Appeal Board

May 17, 2016, Decided

Appeal 2013-009212; Application 12/646,615; Technology Center 3600

Reporter
2016 Pat. App. LEXIS 2105

Ex parte GUY ROBERT VESTO

Notice:
[*1]

ROUTINE OPINION. Pursuant to the Patent Trial and Appeal Board Standard Operating Procedure 2, the opinion below has been designated a routine opinion.

Core Terms

patient, medical case, symptom, unpatentable, calculate, rejected claim, collaborate, recite, label, clinical trial, feature-sets, apparatus, diagnose, medical condition, health issues, prior art, parameter, diagnose, network, module, patent

Panel: Before ANTON W. FETTING, BIBHU R. MOHANTY, and BRADLEY B. BAYAT, Administrative Patent Judges.

Opinion By: ANTON W. FETTING

Opinion

FETTING, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE [1]

Guy Robert Vesto (Appellant) seeks review under *35 U.S.C. § 134* of a final rejection of claims 1-27, the only claims pending in the application on appeal. We have jurisdiction over the appeal pursuant to *35 U.S.C. § 6(b)*.

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[1] Our decision will make reference to the Appellant's Appeal Brief ("App. Br.," filed February 27, 2013) and Reply Brief ("Reply Br.," filed July 12, 2013), and the Examiner's Answer ("Ans.," mailed May 6, 2013), and Final Action ("Final Act.," mailed August

The Appellant invented a form of integrated medical case research and collaboration. Specification para. 1.

An understanding of the invention **[*2]** can be derived from a reading of exemplary claim 1, which is reproduced below (bracketed matter and some paragraphing added).

1. A method to provide medical case research and collaboration, comprising:

[1] generating,

by a processor,

a medical case

based on information related to one or more health issues of a person;

[2] calculating a likelihood

associated with a potential cause of the one or more health issues,

wherein the likelihood is representative of a probability that the potential cause of the one or more health issue is an accurate diagnosis;

[3] determining whether the likelihood indicates that the medical case is complex; and

[4] when the medical case is determined to be complex based on the likelihood, granting the person access to a collaboration module.

The Examiner relies upon the following prior art:

Gray	US 6,149,585	Nov. 21, 2000
Soll	US 7,593,952 B2	Sep. 22, 2009
Boyce	US 2009/0313045 A1	Dec. 17, 2009
Seward	US 2010/0094648 A1	Apr. 15, 2010
Finlay	US 2010/0299155 A1	Nov. 25, 2010

Claims 1, 2, 4-6, 10, 11, 13-15, 26, and 27 stand rejected under *35 U.S.C. § 103(a)* as unpatentable over Soll and Boyce. **[*3]**

Claims 3, 8, 12, 18, and 20-22 stand rejected under *35 U.S.C. § 103(a)* as unpatentable over Soll, Boyce, and Seward.

Claims 7, 9, and 16 stand rejected under *35 U.S.C. § 103(a)* as unpatentable over Soll, Boyce, and Finlay.

Claim 25 stands rejected under *35 U.S.C. § 103(a)* as unpatentable over Soll, Boyce, and Gray.

Claims 17, 19, and 24 stand rejected under *35 U.S.C. § 103(a)* as unpatentable over Soll and Seward.

Claim 23 stands rejected under *35 U.S.C. § 103(a)* as unpatentable over Soll, Seward, and Finlay.

ISSUES

The issues of obviousness turn primarily on the weight to be afforded the labels attached to the recited data and whether the claims are sufficiently broad to encompass the prior art within their scope.

FACTS PERTINENT TO THE ISSUES

The following enumerated Findings of Fact (FF) are believed to be supported by a preponderance of the evidence.

Facts Related to the Prior Art

Soll

01. Soll is directed to disease management by integrating a plurality of separate functions into a seamless diagnostic and treatment system that enhances patient **[*4]** assessment, activates (primes) and educates patients to become maximally involved in their care, and improves the efficiency of physician management process. Soll 1:6-19.

02. Soll's Comprehensive Patient Management ("CPM") system supports a new paradigm of health care delivery by integrating biomedical and psychosocial approaches to patient management and providing tools to improve and measure patient assessment, quality of life, and physician process. Soll 4:37-44.

03. Soll's screening sequence is designed to identify probable symptom complexes. Soll 16:44-46.

04. Multiple, overlapping symptom complexes present a common challenge: they may be separate problems or they may in fact represent the same underlying process. These distinctions have a substantial impact on the diagnostic and therapeutic process. Soll improves the patient's ability to accurately describe multiple, overlapping symptom complexes and the physician's ability efficiently work with this information. Soll 21:36-44.

05. The CPM analysis of symptom complexes reveals situations where symptoms apparently share features. Physicians are informed of any apparent overlap. For example, if the patient has functional **[*5]** symptoms such as heartburn, indigestion, acid dyspepsia, and/or irritable bowel syndrome, this suggests the possibility of a widespread irritable gut. Although organic disease should be considered, this scenario is likely for functional disorders. Soll 22:43-49.

06. Soll describes using a problem list that describes the probability of some diagnoses (e.g. Irritable Bowel Syndrome, Probable) .

Soll 34: 1-35:13.

Boyce

07. Boyce is directed to a network for medical research and clinical trial and to improve targeting of participants, capturing of patient data and better distribution and processing of patient data through a network for medical research and clinical trial. Boyce para. 2.

08. The information to be entered in a database for potential participants should have the data and profiles that are relevant to selecting a participant for a trial. Boyce para. 45.

09. Boyce describes setting, implementing and executing rules related to what may include the selection and qualification of participants. Boyce para. 116.

10. Boyce describes identifying a patient as a potential participant in a clinical trial based on parameters related to the requirements of the clinical **[*6]** trial. Other examples of selection parameters for identifying a potential participant may include: an existing illness, an existing complaint, age, weight, gender, blood-pressure, pulse, temperature, use of drugs, one or more symptoms such as a cholesterol level within a certain range, and one or more symptoms such as a cholesterol level outside a certain range. Boyce para. 119.

11. Boyce describes qualifying the patient as a participant once a patient is identified as a potential participant. A second set of parameters applied to qualify a potential participant as an actual participant may have narrower of broader margins than the first set of parameters. Boyce para. 120.

12. A patient may be identified as having a certain status in a project. A patient may be invited to join a network for clinical trial or medical research. A patient may for instance be invited by a physician or a healthcare provider to join a network. After the patient agrees to join a network, a set of data providing relevant information related to future clinical trials and research is entered. Such data contains age, gender, vitals, occupation, medical history, current symptoms, complaints, use of medication **[*7]** and any other data that may be used to identify a patient as a participant or candidate in a specific project. Such data may be marked for selecting participants in research or a trial. Boyce para. 198.

Seward

13. Seward is directed to the application of complexity science and expert knowledge to analyses of medical data for evaluation of risk for emergent diseases and diagnoses wherein medical data of a person is obtained, feature-sets of associated features of medical conditions are accessed from a medical knowledgebase, and values of the medical data are compared to ranges of values of the features of relevant feature-sets to identify any at-risk medical conditions of the person. Seward para. 1.

14. Seward identifies those feature-sets, i.e., a subset of all feature-sets that have the highest correlation of features with the input medical data of an individual person. Based on the input medical data, one or more feature-sets may be identified. A person's medical data may indicate that the person has one or more medical conditions or disease states. Similarly, the medical data may not correlate with any existing feature-set in the knowledgebase. In this case, the medical **[*8]** data pertaining to the person may be highlighted for further review by a human expert. Thus, the processes and components execute to correlate medical data to features and predict, quantify, and may suggest or monitor treatment for pre-emergent, or emerging or clinically apparent medical conditions and identify possible courses of action. Seward para. 47.

ANALYSIS

Before launching into Appellant's arguments, we initially observe the breadth of claim 1. Claim 1 is a method claim with four steps. The steps are (1) generating a datum A labeled a "medical case; " (2) calculating some likelihood in some unspecified format and manner associated with B labeled potential health issue cause, where the likelihood is in some sense representative of a probability of C, labeled potential cause is an accurate diagnosis; (3) determining whether the likelihood indicates D, labeled the medical case is complex; and (4) when step (3) evaluates as TRUE, granting access to some module labeled collaboration. Thus, the claim is directed to generating a datum and calculating a likelihood represented in some manner of a probability, and using the likelihood as a criterion for granting access to some module. **[*9]** Nothing in the claim requires or enforces the labels as the claim suggests the data to be perceived as. Mental perceptions of what data represents are non-functional and given no weight. *King Pharm., Inc. v. Eon Labs, Inc., 616 F.3d 1267, 1279 (Fed. Cir. 2010)* ("[T]he relevant question is whether 'there exists any new and unobvious functional relationship between the printed matter and the substrate.'") (citation omitted). *See also In re Lowry, 32 F.3d 1579, 1583 (Fed.Cir.1994)* (describing printed matter as "useful and intelligible only to the human mind") (quoting *In re Bernhart, 417 F.2d 1395, 1399 (CCPA 1969)).*

The Examiner finds that Soll describes a patient healthcare system, which by definition stores data regarding patient health; i.e. medical case based information. The system identifies probable symptom complexes and acts to make diagnoses more accurate by separating out underlying health problems. This occurs by revealing situations where symptoms apparently share features that suggest the possibility of specific underlying cause, such as widespread irritable gut. The system also **[*10]** identifies the probability of some diagnoses. Thus, Soll calculates the likelihood associated with such causes and that likelihood is historically representative, that a cause being associated with the specified symptoms, and therefore in that sense representative of the accuracy of such a diagnosis.

The Examiner applies Boyce to show deciding to grant access to a collaborative clinical trial based on the likelihood that a patient meets the criteria for the trial. Such trials are frequently for complex medical issues.

We are not persuaded by Appellants' argument that Soll fails to describe calculating the recited likelihood. App. Br. 13-14. As the claim does not recite any particular calculation, whether the calculation is quantitative or qualitative, how a likelihood or probability is expressed, or even whether the calculation is done mentally or by machine, any evaluation of a likelihood of an accurate diagnosis, which is by definition representative of some probability, is within the scope of the limitation. Soll explicitly describes using a system to assist in determining likely and probable diagnoses. As no particular calculation is recited, any distinction between the likelihood **[*11]** of a symptom being due to a particular cause is within the scope of the likelihood of the cause being an accurate diagnosis. As a mental calculation is within the claim scope; even a physician rough guess at a likelihood is within the scope of claim 1.

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