

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN YUNDT-PACHECO

Appeal 2008-0020
Application 10/428,584
Technology Center 2800

Decided: July 21, 2008

Before JOSEPH F. RUGGIERO, MAHSHID D. SAADAT,
and ROBERT E. NAPPI, *Administrative Patent Judges*.

SAADAT, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

This is a decision on appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1-7, 9, 11-14, 16-22, 24-32, 34-44, 46, and 47. Claims 8, 10, 15, 23, 33, and 45 have been objected to as being dependent upon a rejected base claim, but otherwise allowable if rewritten in

independent form including all the limitations of the base claim and any intervening claims. We have jurisdiction under 35 U.S.C. § 6(b).

Appellant invented a method and system that enables a laboratory to integrate its internal and external quality control programs to thereby control the quality of its laboratory testing services (Spec. 4). An understanding of the invention can be derived from a reading of independent claim 1, which is reproduced as follows:

1. A system for integrating the internal and external quality control programs of a laboratory utilizing control rules for specified laboratory tests, comprising:

at least one storage device;

at least one processor operable to:

maintain in the storage device at least one database identifying a plurality of laboratory tests and corresponding group statistical summary data, the database also identifying the plurality of laboratory tests data and corresponding control rules expressed as a function of the group statistical summary data; and

calculate a control range for a specified one of the laboratory tests by applying the group statistical summary data for the specified laboratory test to the control rule for the specified laboratory test whereby the calculated control range defines an acceptable range of test result values for the specified laboratory test.

The Examiner relies on the following prior art reference:

Lin US 5,532,941 Jul. 2, 1996

Claims 1-7, 9, 11-14, 16-22, 24-32, 34-44, 46, and 47 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lin.

We make reference to the Briefs¹ and the Answer² for their respective details. Only those arguments actually made by Appellant have been considered in this decision. Arguments which Appellant did not make in the Briefs have not been considered and are deemed to be waived. *See* 37 C.F.R. § 41.37(c)(1)(vii).

We affirm and enter a new ground of rejection pursuant to the provisions of 37 C.F.R. § 41.50(b).

ISSUE

Under 35 U.S.C. § 102(b), does Lin have a disclosure which anticipates the invention set forth in the appealed claims?

FINDINGS OF FACT

1. Lin provides for a method and apparatus used in producing quality control evaluation information for each instrument in a large group of instruments making up a peer group which periodically (such as daily) runs a set of control samples from a common lot of control materials. (Abstract).

2. The evaluation relates to monitoring widely dispersed instruments and in a particular embodiment, to inter-laboratory quality control monitoring and reporting for validation of laboratory analyses. (Col. 1, ll. 6-9).

¹ We refer to the revised Appeal Brief, filed on Jul. 8, 2005 and the Reply Brief, filed on Jan. 19, 2006.

² We refer to the Supplemental Examiner Answer, mailed Aug. 3, 2006, which restates the arguments included in the Examiner's Answer, mailed Nov. 17, 2005.

3. Lin uses the concordance correlation coefficient (CCC) as a measure of instrument performance, the CCC serving to evaluate control readings from a given instrument against a golden peer group target determined from a subset of the good performing instruments within the larger group. (Col. 2, ll. 43-48).

4. The control data readings produced by the instruments at widely geographically dispersed locations are input to the system via a communications medium linking all of the instruments to a central station. (Col. 3, ll. 6-11).

5. The central station is made up of a number of modules, including a communication interface, and a data storage module for storing all of the control data received from the dispersed instruments, along with identifiers associating the source of the data with the data itself. (Col. 3, ll. 11-15).

6. A target module operates on the collected data at predetermined intervals, or on demand, and is adapted to establish control targets. (Col. 3, ll. 15-18).

7. The target module operates in conjunction with a status memory which identifies the good performing subset of instruments known as the golden peer group and assists in selecting from the control data storage module the data originating from the golden peer group. That data is processed to produce targets in the target module. (Col. 3, ll. 18-24).

8. A concordance correlation comparator compares the targets (for each day) against the control readings for each instrument for each day over an interval, such as a month producing a concordance correlation coefficient for each instrument for the interval. (Col. 3, ll. 40-44).

9. The concordance correlation coefficient (CCC) rates both the accuracy and the precision of the instrument readings with respect to the golden peer group target reading for the interval in question, and provides a single number for the interval which measures accuracy and precision. (Col. 3, ll. 44-49).

10. As shown in Figure 1, Lin discloses the communication interface over a communication network 30 between the controlling processor 42 in the central station and the instruments in each of laboratories 21a-21n, as well as with the data storage memory 44. (Col. 5. ll. 23-47; col. 7, ll. 9-14).

11. The CCC evaluator 48 provides a quality control rating for each instrument by comparing the single rating number against the CCC distribution for the entire peer group, as shown in chart 49. (Col. 8, ll. 5-11).

12. Chart 49 includes plots 49a-49c which indicate the average as well as the one and two standard deviation (SD) lower limits from the average for determining the performance of each laboratory with respect to the peer group. (Col. 8, ll. 20-45).

13. Lin provides in the target module 160, shown in FIG. 6, an input line 170 for control data which is reported by each instrument across a predetermined time interval. The module 171 determines a weekly moving median (WMM) for each of the instruments, and outputs that median on a daily basis to a weekly moving median storage memory 172. (Col. 16, ll. 25-38).

PRINCIPLES OF LAW

In rejecting claims under 35 U.S.C. § 102, “[a] single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation.” *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1375-76 (Fed. Cir. 2005), citing *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992). “Anticipation of a patent claim requires a finding that the claim at issue ‘reads on’ a prior art reference.” *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1346 (Fed Cir. 1999) (“In other words, if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art.”) (internal citations omitted).

ANALYSIS

Rejection of claims 1, 17, 27, and 37

Appellant does not dispute the teachings of Lin with respect to the external quality control system for monitoring the performance of a large group of laboratory instruments and periodically providing the CCC report to each laboratory (App. Br. 13). However, Appellant’s contentions focus on whether Lin discloses the internal operations of laboratories and/or utilization of the information contained in the performance report (App. Br. 13; Reply Br. 3).

Appellant specifically contends that Lin does not disclose how the laboratories use the CCC report, even if the report may contain “group statistical summary data” since Lin does not discuss the internal operation of

the laboratories or any internal testing based on the control rules (App. Br. 14; Reply Br. 3-4). The Examiner responds (Ans. 22-23) that Lin does maintain a database identifying the laboratory test data collected from a plurality of test data from a specific laboratory. The Examiner specifically asserts that the target module operates on the collected tests from a plurality of the laboratories to establish control targets, which is the same as the claimed target rules (Ans. 22).

We agree with the Examiner's line of reasoning and find that Lin clearly relates to a quality control program of a laboratory wherein a storage device, controlled by a processor, stores group statistical summary data in the form of readings from a golden peer group (FF 1-3). Lin discloses a plurality of tests in the form of the readings from each laboratory (FF 4) which are compared with the golden peer group data as the claimed calculated control range for each laboratory for defining an acceptable range of the test results (FF 5-9). In fact, contrary to Appellant's argument (Reply Br. 3), whether each laboratory utilizes information contained in the CCC report or integrates such information in its internal quality control is not relevant to the recited features, which merely require *calculating a control range* for a laboratory test using the group statistical summary data. As such, while Lin does not focus on any specified laboratory tests, the test results related to each instrument in the remote laboratories are read against the CCC distribution for determining a quality control rating (FF 10-12).

We further observe that the claims require two functions: maintaining a database and calculating a control range. The content of the database in the form of identified tests, test data, and the corresponding control rules and what the control range defines, which are calculated based on the database

content, relate to non-functional descriptive material. The Examiner need not give patentable weight to descriptive material absent a new and unobvious functional relationship between the descriptive material and the method. *See In re Lowry*, 32 F.3d 1579, 1583-84 (Fed. Cir. 1994); *In re Ngai*, 367 F.3d 1336, 1338 (Fed. Cir. 2004) and our recent final decision in *Ex parte Curry*, 84 USPQ2d 1272, 1274 (BPAI 2005), *aff'd* (Fed. Cir. Appeal No. 2006-1003, *aff'd* Rule 36 June 12, 2006).

However, as shown by the Examiner, Lin not only teaches maintaining a database and calculating a control range, but does so by applying the same database content for calculating a control range that defines an acceptable range for the same test. Therefore, for all of the previously discussed reasons, we simply find no error in the Examiner's position that Lin teaches the subject matter of claims 1, 17, 27, and 37 as well as claims 2-4, 7, 9, 11, 13, 14, 16, 18, 21, 22, 24, 26, 28, 29, 31, 32, 34, 36, and 41³ dependent thereon and argued together as falling with their independent base claims (App. Br. 14-15).

Rejection of claims 5, 19, 29, and 38

In support of patentability of claim 5, Appellant argues that the central quality control site 40 of Lin does not generate internal laboratory statistical data for laboratories 21a-21n (App. Br. 15; Reply Br. 5). We disagree. As pointed out by the Examiner (Ans. 24), Figure 6 of Lin shows control data 170 and the golden peer group data 176. Since 170 represents the control data reported by each instrument in laboratories 21a-21n over time for

³ Appellant argues claim 41 as falling with claim 37, although claim 41 depends from claim 40, which is discussed with claim 40 *infra*.

forming statistical summary data related to a specific laboratory (FF 13), Lin teaches that both the group statistical summary data and the internal laboratory statistical data are applied in calculating the control range. We therefore find no error in the Examiner's position that Lin teaches the limitations of claims 5, as well as claims 19, 29, and 38, argued together as falling with claim 5.

Rejection of claims 6, 20, 30, and 39

With respect to claim 6, Appellant argues that Lin does not transfer updated group statistical summary data to a database where it becomes the group statistical summary data (App. Br. 16; Reply Br. 6). The Examiner asserts that the golden peer group data is based on an average value which is updated on a daily basis and later becomes the group statistical summary data and is used in calculating the control range (Ans. 26). We find that Lin updates the golden peer group readings over a period of time and provides a single number to be used as the group statistical summary data (FF 7-9). Therefore, we find no error in the Examiner's position that Lin teaches the limitations of claim 6, as well as claims 20, 30, and 39, which are not argued separately allowing them to fall with claim 6.

Rejection of claims 12, 25, 35, and 40

Regarding claim 12, Appellant argues that Lin does not disclose the internal operations of the laboratories 21a-21n and therefore, cannot determine whether the test results fall within a calculated control range for that test (App. Br. 17; Reply Br. 7). We disagree. As identified by the

Examiner (Ans. 27), Lin provides for a peer group selector 52 and a correlation coefficient evaluator 48 which identify the instrument data that fall within a specific range over time and related to a specific laboratory (FF 11-12). Likewise, we find no error in the Examiner's position that Lin teaches the limitations of claim 12, as well as claims 25, 35, and 40, which are argued as one group together with claim 12.

Rejection of claims 42-44, 46, and 47

Appellant relies on the same arguments made with respect to claims 1, 6, and 12 and contends that Lin does not teach all the limitations of claim 42 and relies on the arguments related to claim 5 to assert patentability of claim 43 (App. Br. 18-19; Reply Br. 7-9). For the same reasons discussed above with respect to claims 1 and 5, we find no error in the Examiner's position that Lin teaches the limitations of claims 42 and 43, as well as claims 44, 46, and 47, which are not argued separately.

CONCLUSION

On the record before us, Appellant has failed to show that the Examiner erred in rejecting the appealed claims. In view of our analysis above, we sustain the 35 U.S.C. § 102 rejection of claims 1-7, 9, 11-14, 16-22, 24-32, 34-44, 46, and 47.

NEW GROUND OF REJECTION

We enter the following new rejections for claims 8 and 15 under the provisions of 37 C.F.R. § 41.50 (b).

Claim 15 is rejected under 35 U.S.C. § 102(b) as being unpatentable over Lin.

The recited central storage device and the central processor located at a central agency are disclosed by Lin as the central station that includes several modules or components. The central station of Lin contains the system central processor 42 and the system storage module 44 (FF 4-7, 10).

Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin.

Lin uses a communication network 30 for transmitting the test result to the central quality control site, which includes communication links established on the public telephone system accessed by dialing up through the normal commercially available telecommunication channels (FF 10). Although Lin does not specify using Internet, one of ordinary skill in the art would have considered transmitting data over the Internet as one of the normal commercially available telecommunication channels suggested by Lin. Additionally, dialing up through these channels implies communication over a network which includes Internet as one of the available channels known in the art.

For the above reasons, we find that claims 8 and 15 recite limitations that are disclosed or suggested by Lin. Accordingly, claim 8 is rejected under 35 U.S.C. § 103(a) and claim 15 is rejected under 35 U.S.C. § 102(b) over Lin.

DECISION

The decision of the Examiner rejecting claims 1-7, 9, 11-14, 16-22, 24-32, 34-44, 46, and 47 under 35 U.S.C. § 102 based on Lin is affirmed. Moreover, we have entered new grounds of rejection under 37 C.F.R.

Appeal 2008-0020
Application 10/428,584

§ 41.50(b) for claims 8 and 15 as being unpatentable under 35 U.S.C. §§ 103 and 102, respectively.

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

- (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
- (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED - 37 C.F.R. § 41.50(b)

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