Paper No. 45

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOHN A. McNEIL, MICHAEL A. AKONG, DONALD J. MIERZESKI, GONUL VELICELEBI and DAVID P. KARLTON

Appeal No. 2003-1017
Application No. 08/287,358

HEARD: October 21, 2003

Before WILLIAM F. SMITH, SCHEINER and GRIMES, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 15, 17-28, 32-39 and 41-44, the only claims remaining in the application. Claims 15, 19, 32 and 36 are representative of the subject matter on appeal:

15. A method for simultaneously performing a plurality of fluorescence assays using a multi-well plate containing a plurality of wells distributed throughout at least a portion of said multi-well plate, said method comprising the steps of:
distributing a predetermined amount of a liquid to a number of said plurality of wells;
projecting excitation radiation uniformly onto the portion of said multi-well plate throughout which the plurality of wells are distributed, thereby simultaneously and uniformly illuminating both said plurality of wells and the portion that is disposed between each of said plurality of wells;
receiving an image of fluorescence emitted from said plurality of wells simultaneously over a predetermined period of time; and
processing fluorescence data from the image.

19. A method for simultaneously performing a plurality of signal-based assays, each of said plurality of assays performed in one of a plurality of wells on a multi-well

plate, said method comprising the steps of:

distributing a predetermined amount of a liquid to a number of said plurality of wells;

receiving an image of emissions emitted from said plurality of wells simultaneously over a predetermined period of time, the image comprising an entire view of each of the plurality of wells; and

processing emissions data from the received image.

32. A method for scheduling and performing a plurality of fluorescence assays using a plurality of plates each including a plurality of wells, the method comprising the steps of:

storing data representing at least first and second tracks and at least one critical point at which the first and second tracks are tied together in time, each of the first and second tracks defining a set of assay operations in time, at least a portion of the set of assay operations of the first track to be performed simultaneously with the second track; and

performing at least a portion of the sets of assay operations on at least one of the plates such that a portion of the set of assay operations of the second track defined prior to the at least one critical point is finished before beginning a portion of the set of assay operations of the first track defined after the at least one critical point.

36. A method for simultaneously performing a plurality of fluorescence assays using a plate containing a plurality of wells, the method comprising the steps of:

detecting fluorescence emitted from each of the plurality of wells; and

displaying in real or pseudo real time a graphical representation of the fluorescence emitted from each of the plurality of wells, the graphical representation indicating an arrangement in the plate of the plurality of wells.

The references relied on by the examiner are:

Tillotson	5,053,626	Oct. 1, 1991
Chow et al. (Chow)	5,112,134	May 12, 1992
Bjornson et al. (Bjornson)	5,125,748	Jun. 30, 1992
Ellis et al. (Ellis)	5,407,820	Apr. 18, 1995
Akong et al. (Akong)	WO 93/13423	Jul. 8, 1993

The claims stand rejected as follows:

I. Claims 15, 17-28, 36-39 and 41-44 under 35 U.S.C. § 102 (b) as anticipated by Akong.

II. Claims 15, 18-23, 27, 28, 32-38, 41 and 42 under 35 U.S.C. § 103 as unpatentable over Bjornson and Chow.

III. Claims 24-26, 43 and 44 under 35 U.S.C. § 103 as unpatentable over Bjornson, Chow and Ellis.

IV. Claims 17 and 39 under 35 U.S.C. § 103 as unpatentable over Bjornson,

Chow and Tillotson.

We reverse all of these rejections.

DISCUSSION

> [In the] type of [signal-generating] assay . . . referred to as an endpoint assay . . . the signal is allowed to develop over time, and then a single measurement is taken after the reaction is complete in order to quantify the property.
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> In contrast to attributes that can be measured in endpoint assays, there are many properties, reactions and biological events that are dynamic and transient and/or rapidly occurring.
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> * * *
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> [T]he signal generated in these assays is rapidly occurring and transient, as is the phenomenon itself. Thus, . . . if initiation of the reaction or event . . . is not coordinated with almost immediate signal detection in a dynamic fashion, the signal may reach a maximum and diminish before it is detected . . . [T]o perform large-scale compound screening, coordination of sample handling and signal detection must be accomplished for many assays simultaneously. Furthermore, it is desirable to obtain a real-time record of each event until it has progressed to a point beyond that of maximum signal change . . . [t]he duration, as well as the timing, of signal measurement poses an additional complication . . . since the signal must be measured essentially constantly.

Specification, pages 1-3.

"The present invention provides an integrated sample handling and detection system that enables simultaneous preparation and performance of multiple assays of rapidly occurring, transient phenomena in a plurality of individual wells of a test plate; imaging of the assays . . . continuously and in real time over a period of time; and collection, storage, and analysis of the imaging data" (Specification, page 4). In addition, "the projection system of [the] excitation source is designed to provide uniform illumination to the bottom of [a multi]-well plate" (id., page 17), thus, "the excitation and detection systems . . . ha[ve] sufficient flexibility to read any desired plate format" and "[t]he number of wells that can be read simultaneously is only limited by the camera's

resolution" (id., page 16).

Anticipation

"[E]very limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). Moreover, "the Patent Office has the initial burden of coming forward with some sort of evidence tending to disprove novelty." In re Wilder, 429 F.2d 447, 450, 166 USPQ2d 545, 548 (CCPA 1970).

Claims 15, 17-28, 36-39 and 41-44 stand rejected under 35 U.S.C. § 102 (b) as anticipated by Akong. Claims 15, 17, 18, 27, 28, 39 and 41 require, inter alia, projecting excitation radiation uniformly onto a multi-well plate, thereby illuminating both the wells and the portion of the plate disposed between the wells; claims 19-26 and 42-44 require receiving an image of emissions from multiple wells simultaneously over a period of time, wherein the image comprises an entire view of each of the wells; and claims 36-38 require displaying a graphical representation of fluorescence emitted from each well of a multi-well plate, in real or pseudo real time, wherein the graphical representation indicates the arrangement of the wells on the plate. Although the examiner does not address any of these limitations in the statement of the rejection (Answer, pages 4-5), he nevertheless concludes that "[a]ll the features of the present claims are taught by Akong for the same function as presently claimed" (id., page 5).

Appellants argue that Akong fails to disclose "projecting excitation radiation uniformly in the manner [required]" (Brief, page 29); moreover, Akong does not disclose "receiving an image of each of a plurality of wells, [much less] an image comprising an entire view of each of the wells" (id., page 31). "[I]nstead[, Akong] discloses individual

fiber-optic light sources and detectors dedicated to illuminating and detecting individual wells" (id.). Finally, appellants argue that Akong "fails to teach or suggest displaying a graphical representation indicating the arrangement in the plate of a plurality of wells" (id., page 33).

In response, the examiner offers several irrelevant arguments. First, that "[Akong's] apparatus can align one or more different wells to be assayed . . . [which] would then encompass exciting and reading any number of wells in a given plate" (Answer, page 10); that "the teachings of Akong would inherently configure exciting and reading wells irrespective of their arrangements" (id., page 11); and finally, that "the data obtained from the apparatus of Akong is generally charted as a curve and may be charted in real time or not . . . [n]o novelty is seen in charting data real time" (id.).

The examiner's conclusory statements and irrelevant arguments are insufficient to discharge the Office's initial burden of establishing a prima facie case of anticipation. Accordingly, we reverse the rejection of claims 15, 17-28, 36-39 and 41-44 under 35 U.S.C. § 102(b) as anticipated by Akong.

Obviousness

The claims stand rejected as follows: claims 15, 18-23, 27, 28, 32-38, 41 and 42 as unpatentable over Bjornson and Chow; claims 24-26, 43 and 44 as unpatentable over Bjornson, Chow and Ellis, and claims 17 and 39 as unpatentable over Bjornson, Chow and Tillotson. The salient limitations of claims 15, 17-28, 36-39 and 41-44 are discussed above. Claims 32-35, directed to a method for scheduling and performing a plurality of fluorescence assays using a plurality of plates each including a plurality of wells, require

> storing data representing at least first and second tracks and at least one critical point at which the first and second tracks are tied together in time,

> each of the first and second tracks defining a set of assay operations in time, at least a portion of the set of assay operations of the first track to be performed simultaneously with the second track; and performing at least a portion of the sets of assay operations on at least one of the plates such that a portion of the set of assay operations of the second track defined prior to the at least one critical point is finished before beginning a portion of the set of assay operations of the first track defined after the at least one critical point.

Without belaboring the point any more than is necessary, we note that none of the three obviousness rejections addresses the limitations mentioned above, and again, the examiner's response to appellants' pointed arguments is conclusory and/or irrelevant. For example, in response to appellants' argument that neither Bjornson nor Chow teaches or suggests the uniform illumination required by certain of the claims (Brief, page 35), the examiner asserts that Chow's multiple "photometric devices are capable of simultaneously performing individual assays . . . [which] would read on 'illuminating both said plurality of wells and all of the portion that is disposed between each of said [ ] wells'" and that, in any case, "[n]o criticality to the limitation is seen" (Answer, pages 12-13). Nevertheless, the examiner does not identify any evidence that Chow teaches or suggests uniform illumination, whatever the theoretical capabilities of his photometric devices. Moreover, the "criticality" of a limitation is irrelevant if there is nothing stemming from the prior art to suggest it in the first place.

Similarly, apparently in response to appellants' assertion that neither Bjornson or Chow "teaches receiving an image of each of a plurality of wells, let alone an image comprising an entire view of each of the wells" (Brief, page 36), the examiner argues "as [the claims are] written, the limitations read on multiple fibers aligned with a plurality of wells with a single or multiple light source" and Bjornson "impl[ies] that more than one sample at a time may be measured," while Chow's multiple "photometric devices are

capable of simultaneously performing individual assays on a plurality of . . . samples" (Answer, page 12). Even if we assume that the examiner is correct on these points, his response still fails to address the requirement for receiving an image from each of the wells, and is therefore unpersuasive. Finally, we cannot agree with the examiner's conclusion that "only meaningful data is obtained from emissions from wells and therefore obtaining such data would render obvious view of the entire surface of the plate" (id., page 13).

Appellants also note that claims 32-35 were rejected as unpatentable over the combined teachings of Bjornson and Chow, but "the examiner did not even hint at why such a rejection was made" (Brief, page 36). The only response we see from the examiner is an irrelevant assertion that "the unexpected result of claim 32 where the scheduler optimizes something is not found in the claims or specification" (Answer, page 13).

35 U.S.C. § 103 requires that obviousness be determined based on the claimed subject matter as a whole. Where, as here, the determination of obviousness is based on less than the entire claimed subject matter, the examiner's conclusion of obviousness is unsound and cannot stand. On this record, we hold that the examiner has not established a prima facie case of obviousness for even the broadest claims on appeal. Accordingly, the rejections of the claims under 35 U.S.C. § 103 are reversed.

REVERSED

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William F. Smith)
Administrative Patent Judge)
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