

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PETER G. WEBB

Appeal 2008-0140
Application 09/772,723
Technology Center 1600

Decided: March 31, 2008

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of generating an addressable array of biopolymers. The Examiner has rejected the claims as obvious and as lacking an adequate written description in the Specification. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

“Arrays of biopolymers, such as arrays of peptides or polynucleotides (such as DNA or RNA), are known and are used, for example, as diagnostic or screening tools” (Spec. 1). In array fabrication, “it will often be desirable

to have the arrays fabricated at a fabrication facility and then shipped to the end user,” thus requiring “a customer to ship the various biopolymers used to fabricate the array to the fabrication facility” (*id.*). “One convenient way of supplying the biopolymers is in multiple 96 well trays,” although “[i]t may not always be possible or desirable to deposit the biopolymers to form the array in blocks of 96 due to limitations of the fabricating apparatus. In such cases, it would be desirable if the customer ... [had a] way of correlating the biopolymers provided to the features of a fabricated array” (*id.*).

The Specification discloses “a method of producing an addressable array of biopolymers ... on a substrate. ... The method includes obtaining the biopolymers from individual identified vessels” and depositing them “onto different regions of the substrate so as to fabricate the array. A map of the identity of the vessels to the corresponding regions of the substrate ... is saved in a memory in association with a map identifier. The map identifier may be applied to the substrate or a housing carrying the substrate” (*id.* at 3).

DISCUSSION

1. CLAIMS

Claims 1-14 and 45-54 are pending and on appeal. Claims 1, 4, 45-48, 53 and 54 are representative and read as follows:

Claim 1: A method of generating an addressable array of biopolymers on a substrate, comprising:

- (a) providing a plurality of individual vessels each containing a biopolymer wherein said plurality is provided in a defined format;
- (b) assigning a unique format identifier to each member of said plurality;
- (c) obtaining the biopolymers from the plurality of individual identified vessels;

(d) depositing the biopolymers onto different regions of the substrate so as to fabricate the array;

(e) saving in a memory a map of the identity of the vessels to the corresponding regions of the substrate onto which the biopolymers from respective vessels are deposited, in association with a map identifier, wherein said map of the identity of the vessels comprises a unique format identifier of each vessel of said plurality;

(f) applying the map identifier to the substrate or a housing carrying the substrate;

(g) shipping the fabricated array with applied map identifier to a remote location.

Claim 4: A method according to claim 1 wherein the memory is a database, the method additionally comprising obtaining the identity map from the memory and communicating the identity map to a remote location in response to receiving a communication of the map identifier from the remote location.

Claim 45: The method according to Claim 1, wherein said plurality of individual identified vessels is in a format of a tray with multiple wells.

Claim 46: The method according to Claim 45, wherein said multiple wells are arranged in said tray in rows and columns.

Claim 47: The method according to Claim 46, wherein said individual identity of each vessel is an identifier in the format of: tray number, column number and row number.

Claim 48: The method according to Claim 46, wherein said individual identity of each vessel is an identifier assigned to each vessel relative to a reference mark.

Claim 53: The method according to Claim 1, said method additionally comprising receiving said array and map identifier and using said map identifier to identify vessels corresponding to regions of the array.

Claim 54: A method of generating an addressable array of biopolymers on a substrate, comprising:

(a) obtaining the biopolymers from a plurality of individual identified vessels, wherein each of said vessels is marked with a unique identifier that is not composition information from that vessel;

(b) depositing the biopolymers onto different regions of the substrate so as to fabricate the array;

(c) saving in a memory a map of the identity of the vessels to the corresponding regions of the substrate onto which the biopolymers from respective vessels are deposited, in association with a map identifier, wherein said map of the identity of the vessels comprises an individual identity of each vessel of said plurality;

(d) applying the map identifier to the substrate or a housing carrying the substrate; and

(e) shipping the fabricated array with applied map identifier to a remote location.

2. WRITTEN DESCRIPTION

Claim 54 stands rejected under 35 U.S.C. § 112, first paragraph, on the basis that it lacks adequate written description in the Specification. The Examiner finds that, “[b]ecause there is a lack of written basis for the phrase ‘wherein each of said vessels is marked with a unique identifier that is not composition information from that vessel’ as stated in claim 54, this amended limitation is considered to be NEW MATTER” (Ans. 4).

Appellant argues that throughout the Specification, the unique identifier is described “as specifically marking an individual vessel from the plurality of vessels provided” (Appeal Br. 11). Appellant further argues that the Specification (citing p. 10, ll. 17-22) and the exemplary embodiment shown in Table 1 of the Specification (p. 11) make “clear that the unique identifier is an identifying mark with respect to the specific location of a specific vessel, e.g., ‘tray number, column number, row number,’” and “that the unique identifier does not include compositional information from the vessel itself” (Appeal Br. 11-12).

The purpose of the written description requirement is to “ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor’s contribution to the field as far as described in the patent specification.” *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000). To that end, to satisfy the written description requirement, the inventor “must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). “One shows that one is ‘in possession’ of *the invention* by describing *the invention*, with all its claimed limitations.” *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

We agree with Appellant that the Specification provides adequate descriptive support for the disputed limitation. The Specification discloses in the embodiment shown in Table 1 (Spec. 11) that the vessel identifiers are the tray, column, and row number of the microtitre plate in which the samples were provided and do not contain composition information (*see also* Spec. 10: 20-24). Given this description of the vessel identifiers, we conclude that the written description of the invention, as originally filed, conveys to those of skill in the art that the inventor was in possession of the claimed invention at the time the application was filed.

The rejection of claim 54 under 35 U.S.C. § 112, first paragraph, on the basis of lack a written description in the specification is reversed.

3. OBVIOUSNESS

Claims 1-14 and 45-54 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Hunkapiller¹, Zeleny², Brown³, Anderson⁴, Shakib⁵, and Balaban⁶.

Appellant has argued the claims in eight groups as follows: (i) claims 1-3 and 8-10; (ii) claims 4-7 and 11-14; (iii) claims 45 and 49; (iv) claims 46 and 50; (v) claims 47 and 51; (vi) claims 48 and 52; (vii) claim 53; and (viii) claim 54. The claims in each group stand or fall together (37 C.F.R. § 41.37(c)(1)(vii)).

The Examiner relies on Hunkapiller as disclosing the creation of “arrays with addressable locations where multiple biopolymer samples can be fixed or mounted in fixed locations” and that liquid reagents are “delivered from vessels to solid supports ... which include addressable arrays ... which represents obtaining and providing a plurality of individual vessels” (Ans. 5). The Examiner also finds that Hunkapiller discloses “placing vessels in cooling/heating zones, such as heating blocks ... which represents providing a plurality of vessels in a defined format” (*id.*).

The Examiner finds that Hunkapiller does not describe “saving in a memory a map of the identity of the vessels corresponding to substrate regions where the biopolymers are deposited, applying the map identifier to the substrate or housing carrying the substrate, or shipping the fabricated

¹ Hunkapiller et al., US 5,942,609, Aug. 24, 1999

² Zeleny et al., US 6,215,894 B1, Apr. 10, 2001

³ Brown et al., US 5,807,522, Sep. 15, 1998

⁴ Anderson, US 6,456,942 B1, Sep. 24, 2002

⁵ Shakib et al., US 5,812,793, Sep. 22, 1998

⁶ Balaban et al., US 6,229,911 B1, May 8, 2001

array with applied map identifier to a remote location” (*id.*) as recited in claim 1.

The Examiner relies on Zeleny for disclosing “an identifier corresponding to each experiment imprinted on [a] biochip” (Answer 5) and “a computer-stored record corresponding to each identifier” (*id.* at 6). The Examiner also finds that Zeleny discloses that the computer-stored record may contain “various parameters of the experimental array including a map of the reagents deposited in the array” (*id.*).

The Examiner relies on Brown as disclosing the “mass fabrication of microarrays . . . and shipment of DNA reagents via microarrays to researchers” (*id.*).

The Examiner relies on Anderson for disclosing “a server that designs a set of probes to capture target sequences requested by a user, a synthesizer (fabrication station) that builds the probes on the surface of an array, and a chip that is shipped to a user” (*id.*). The Examiner relies on Balaban and Shakib for disclosing limitations of dependent claims (*id.* at 6-8).

The Examiner concludes that it “would have been obvious to one of ordinary skill in the art at the time of the invention to add automated techniques, beginning with the automated delivery of liquid reagents from vessels to the array, as stated by Hunkapiller . . . using barcode identifiers and mapping reagent location as stated by Zeleny” (*id.* at 8). The Examiner finds that the skilled artisan would have been motivated to do so in order to avoid unnecessary error and to speed efficiency because Zeleny discloses that the “analysis of raw data from a biochip array collected by a scanner was previously performed manually which involved significant operator time as well as errors in the scanning and analysis procedure” (*id.*).

Finally, the Examiner concludes that it “would have been further obvious to the person of ordinary skill in the art to mass fabricate and ship the completed microarrays” as disclosed by Brown because one would be motivated by the desire of researchers to perform numerous genetic applications including genome mapping and medical diagnosis, as disclosed by Brown (*id.*).

We conclude that the Examiner has set forth a prima facie case that claim 1 would have been obvious to the ordinary artisan. Hunkapiller teaches methods of making addressable arrays of biopolymers (Hunkapiller, col. 3, ll. 35-47; col. 18, ll. 11-18). We agree with the Examiner that Hunkapiller’s description of automated assembly, including placing reaction vessels in “cooling/heating zones, e.g. heating blocks, ovens, chillers” (*id.* at col. 17, ll. 52-66) describes a plurality of vessels in defined format, as recited in claim 1.

Zeleny discloses that “[m]icroarray biochips are available in a variety of form[s]” and that the “reagents involved in the chemical reactions in the array dots are typically biological samples such as DNA, RNA, peptides, proteins or other organic molecules” (Zeleny, col. 1, ll. 47-52). Zeleny also discloses that an “experiment identifier is imprinted on the chip prior to the deposition of the array experiment. A file folder (i.e., ‘directory’) is opened in a computer system and is logically linked to the array identifier. An operator may enter into that folder the various parameters of the experiment array, e.g., a map of the reagents deposited in the array.” (*Id.* at col. 2, ll. 18-24.)

Brown discloses that an efficient prior art technique “for making ordered arrays of genomic fragments uses an array of pins dipped into the wells, e.g., the 96 wells of a microtitre plate, for transferring an array of samples to a substrate” (Brown, col. 1, l. 64 to col. 2, l. 1). Brown also discloses an automated “method and apparatus for forming microarrays of biological samples on a support . . . involv[ing] dispensing a known volume of a reagent at each selected array position, by tapping a capillary dispenser on the support under conditions effective to draw a defined volume of liquid onto the support” (*id.*, abstract).

Anderson discloses “methods for interfacing computer technology with biological and chemical processing and synthesis equipment” preferably in a remote manner (Anderson, abstract). Anderson also discloses that, in one embodiment, “a user submits a list of target sequences of interest through a network server; the server designs a set of probes to capture the target sequences and submit that list of probes to the synthesizer; the synthesizer builds the probes on the surface of an array; [and] the chip is shipped to the user” for performance of a hybridization experiment (*id.* at col. 2, ll. 57-63).

We agree with the Examiner that it would have been *prima facie* obvious to one of skill in the art to combine the teachings of Hunkapiller, Zeleny, Brown, and Anderson and thereby arrive at the invention of claim 1. Hunkapiller discloses method of making an addressable array of biopolymers using vessels in a defined format. Zeleny discloses imprinting an identifier on the biochip, and creating a computer record corresponding to the identifier (e.g., a map of the reagents deposited in the array). Brown

discloses that microtitre plates are known for use in the fabrication of arrays, where the contents of each well in a microtitre plate corresponds to a single spot on an array.

In view of the teaching in Brown of the one-to-one correspondence between wells of a microtitre plate and spots on an array and the teachings of Zelany, one of skill in the art would have considered it obvious to store in a computer record a map of reagents deposited on an array that refers to the microtitre wells (i.e., tray number and column and row number) from which the reagents in each spot were obtained. The cited references show that the other steps recited in claim 1 – fabricating an array (e.g., Hunkapiller, Brown), applying a map identifier to a substrate (Zelany), and shipping a fabricated array (e.g., Brown) – are conventional in the art.

Appellant argues that there is no teaching or suggestion in the combination of cited references of the element of assigning unique format identifiers to a plurality of source vessels and saving in a memory a map of the unique format identifiers and corresponding substrate regions (Appeal Br. 17). Appellant further argues that the instantly claimed “unique format identifier” is distinguishable from Zeleny's “experiment identifier” because the vessel identifier is the unique format identifier assigned to the original vessel prior to fabrication of the array (*id.* at 19).

We are not persuaded by this argument. It is true that none of the cited references expressly suggest that the map of the reagents deposited on the array is a map of the source vessel unique format identifiers and corresponding substrate regions, but the prior art need not expressly suggest an invention in order to have made it obvious. “[T]he ‘motivation-

suggestion-teaching' test asks not merely what the references disclose, but whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims." *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006). *See also KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007) (The obviousness analysis "can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.").

Zeleny teaches a computer-stored map of the reagents on an array and Brown teaches a one-to-one correspondence between material transferred from microtitre wells to spots on an array. In addition, it is well known in the art that microtitre plates typically contain unique identifiers for each well of a particular tray such as column and row number. Based on these teachings and the knowledge of those skilled in the art, the claimed feature of assigning unique format identifiers to a plurality of source vessels and saving in a memory a map of the source vessel identifiers for each corresponding substrate region would have been obvious to a person skilled in the art for the reasons stated by the Examiner (Ans. 8).

With respect to claim 4, Appellant argues that the claim further specifies "additional features relating to saving the identity map in a memory and communicating the identity map to a remote location" (Appeal Br. 20). Appellant argues that "because the cited references fail to teach or suggest saving in a memory a map of the unique format identifiers assigned to each original source vessel as is claimed, (discussed above), they likewise fail to

teach or suggest the additional features relating to saving the identity-map in a memory and communicating the identity map to a remote location” (*id.*).

We are not persuaded by this argument. As discussed above, we find that the references suggest saving in a memory a map of the unique format identifiers assigned to each original source vessel. Further, in view of the Anderson’s disclosure of methods for remotely interfacing computer technology with biological and chemical processing and synthesis, and communicating via a network server, one of skill in the art would have considered the claimed feature of “obtaining the identity map from the memory and communicating the identity map to a remote location in response to receiving a communication of the map identifier from the remote location” to be obvious because of the advantages described by Anderson (*see* Ans. 10).

With respect to claims 45-47, Appellant argues that “the references neither teach nor suggest a method wherein the plurality of individual identified vessels is in a format of a tray with multiple wells” (Appeal Br. 21) (claim 45), or that the “multiple wells are arranged in said tray in rows and columns” (*id.*) (claim 46), or that the “individual identity of each vessel is an identifier in the format of: tray number, column number and row number” (*id.*, emphasis deleted) (claim 47).

We are not persuaded by this argument. As discussed above, Brown specifically discloses that reagent samples for array formation may be transferred from microtitre wells to a substrate to form the array. Microtitre plates are well known in the art to contain markings to identify each well, such as by column and row letters and numbers. Thus, one of skill in the art would have considered the additional features recited in claims 45-47 to be

obvious in view of the cited references because multiple wells with rows and columns were conventional formats from which reagents are dispensed.

With respect to claim 48, Appellant further argues that the references do not teach or “suggest a method wherein the individual identity of each vessel is an identifier assigned to each vessel relative to a reference mark” (Appeal Br. 22).

We are not persuaded by this argument. For any given microtitre plate, the identity for each well (i.e. vessel) would be assigned relative to reference marks of the column number and row number assigned to the first well, i.e. the well at column 1, row 1. Thus, one of skill in the art would have considered the claimed feature that the “individual identity of each vessel is an identifier assigned to each vessel relative to a reference mark” to be obvious in view of the cited references.

With respect to claim 53, Appellant further argues that cited references do not teach or suggest the claimed limitation of “additionally comprising receiving said array and map identifier and using said map identifier to identify vessels corresponding to regions of the array” (Appeal Br. 23).

We do not find this argument to be persuasive. Anderson specifically teaches that an array formed at a fabrication site is shipped to the user for hybridization experiments, and thus Anderson clearly teaches the claimed limitation.

With respect to claim 54, Appellant further argues that the claim requires “that each of the individual identified vessels is marked with a unique identifier that is not composition information from that vessel” and

that the cited references neither teach nor suggest this limitation (Appeal Br. 23-24).

This argument is also not persuasive. As discussed above, Brown teaches that it is known in the art to transfer array reagents from microtitre wells to array substrates, and it is well known in the art that microtitre plates are typically marked with row and column numbers to indicate a specific identity for each well. Thus, the claimed limitation is clearly suggested by the cited references.

SUMMARY

The Examiner's obviousness rejection is supported by the preponderance of the evidence of record. We therefore affirm the rejection of claims 1-14 and 45-54 under 35 U.S.C. § 103. However, we reverse the rejection of claim 54 under 35 U.S.C. § 112, first paragraph.

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

AFFIRMED

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AGILENT TECHNOLOGIES
Legal Department, 51U-PD
Intellectual Property Administration
P.O. Box 58043
Santa Clara CA 95052-8043