



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 95/000,529 | 02/19/2010 | 6831994 | 048522-0003 | 8420 |
| 22922 | 7590 | 02/26/2013 | EXAMINER | |
| REINHART BOERNER VAN DEUREN S.C. ATTN: AMANDA RUTTER, PARALEGAL 1000 NORTH WATER STREET SUITE 2100 MILWAUKEE, WI 53202 | | | LEUNG, CHRISTINA Y | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3992 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 02/26/2013 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Illumina, Inc.
(Patent Owner and Appellant)

v.

Life Technologies Corporation
(Requester and Cross-Appellant)

Appeal 2012-010385
Reexamination Control No. 95/000,529
US Patent 6,831,994 B2
Technology Center 3900

Before RICHARD M. LEBOVITZ, JEFFREY B. ROBERTSON, and
RAE LYNN P. GUEST, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

Appeal 2012-010385
Reexamination Control No. 95/000,529
US Patent 6,831,994 B2

This is a decision on appeal in an inter partes reexamination of U.S. 6,831,994 B2. The Patent Owner appeals the Examiner's decision to reject claims as anticipated and obvious. The Third Party Requester cross-appeals the Examiner's determination not to adopt rejections of claims as obvious and the Examiner's withdrawal of the rejection for impermissibly broadening the scope of the claims. The Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315. We reverse and enter new grounds of rejection.

STATEMENT OF THE CASE

The patent in dispute in this appeal is U.S. Patent No. 6,831,994 B2, issued December 14, 2004 (hereinafter, "the '994 patent"). The Patent Owner and Real Party in Interest is Illumina, Inc. ("Illumina"). Illumina's Appeal Brief 2, September 13, 2011 ("Illumina Appeal Br.").

A replacement request for inter partes reexamination of the '994 Patent was filed on February 19, 2010 by a Third-Party Requester under 35 U.S.C. §§ 311-318 and 37 C.F.R. §§ 1.902-1.997. Request for Inter Partes Reexamination 1. The Third-Party Requester is Life Technologies Corporation ("Life"). Life Respondent Brief 1, October 12, 2011 ("Life Resp't Br.").

The '994 patent was the subject of litigation in *Life Technologies Corp. v. Illumina, Inc.*, No.1:09-cv-00706-RK (D. Del., filed September 21, 2009). The Delaware Court issued a claim construction order on December 15, 2010. On April 6, 2011, the Delaware District Court ordered the transfer

Appeal 2012-010385
Reexamination Control No. 95/000,529
US Patent 6,831,994 B2

of the litigation to the Southern District of California, where the case is designated 3:11-cv-00703-JAH-POR. Illumina Appeal Br. 2.

Related U.S. Patent 6,654,505 was subject of inter partes reexamination, Application 95/001,292. An appeal was decided in that case. *Decision on Appeal* in Appeal No. 2012-007309, mailed November 29, 2012.

In the present reexamination appeal, an oral hearing took place on December 13, 2012. A transcript of the oral hearing was entered into the record on January 24, 2013.

Claims

Claims 1-35 are pending. Claims 1-24, 26-30, and 33-34 stand rejected by the Examiner. Claims 25, 31, and 35 are allowed by the Examiner. Claim 32 is canceled. The rejections by the Examiner of claims 1-24, 26-30, and 33-34 are appealed by Illumina. Illumina App. Br. 5. Life cross-appeals the Examiner's determination not to adopt proposed rejections of the claims. Life Technologies Appeal Brief 5, filed October 13, 2011 ("Life Appeal Br.").

Claim 1 reads as follows (bracketed numerals added for reference to the main limitations; underlining indicates amendments relative to the original claims):

1. A system for detecting a sequence of optical signals from each of a plurality of microparticles during a sequence of processing steps, the system comprising:
 - [1] a planar array of uniformly sized spherical microparticles, wherein the coefficient of variation of the diameters of said microparticles is less than five percent;
 - [2] an optical train effective to collect and focus the sequence of optical signals from the microparticles, and to

record at least one optical characteristic of each microparticle which can be used to determine the approximate center of said microparticle;

[3] an imaging device onto which said signals are focused, effective to generate and record a sequence of digital images of the microparticles, with sufficient resolution for individual microparticles to be distinguished; and

[4] signal tracking means effective to correlate the optical signals from each of the microparticles in each of the sequence of digital images with said center of said microparticle.

7. (Amended) The system of claim 1, wherein the system is configured to designate a first pixel for determining characteristics of an optical signal generated at a microparticle, the first pixel being correlated with the center of the microparticle.

APPEAL BY ILUMINA

Illumina appeals the following rejections by the Examiner (Illumina Appeal Br. 5):

1. Rejection of claims 1-4, 6, 14-24, 26-30, and 33-34 under 35 U.S.C. § 102 as anticipated by Brenner;¹
2. Rejection of claims 7-10 and 13 under 35 U.S.C. § 103 as obvious over Brenner in view of Schmidt;²
3. Rejection of claims 7-10 and 13 under 35 U.S.C. § 103 as obvious over Brenner in view of Gelles;³

¹ Sydney Brenner, *Molecular Tagging System*, WO 96/12014 (published April 25, 1996) (Brenner).

² Christine E. Schmidt et al., *Integrin-Cytoskeletal Interactions in Migrating Fibroblasts are Dynamic, Asymmetric, and Regulated*, J. Cell Biology, 123(4):977-991, 1993 (Schmidt).

4. Rejection of claims 7-12 under 35 U.S.C. § 103 as obvious over Brenner in view of Hicks;⁴ and

5. Rejection of claim 5 under 35 U.S.C. § 103 as obvious over Brenner in view of Hansen.⁵

CLAIM INTERPRETATION

Limitation [4] of claim is in dispute in this appeal. We thus begin by construing limitation [4] in view of the '994 patent specification.

The term “signal tracking means” is a means-plus-function term that invokes 35 U.S.C. §112 ¶ 6. Its scope defined by the structure disclosed in the specification plus any equivalents of that structure. *See In re Donaldson*, 16 F.3d 1189, 1195 (Fed. Cir. 1994) (en banc).

The '994 patent specification does not use the term “signal tracking means.” However, it does describe the function of the signal tracking means recited in the claim (“to correlate the optical signals from each of the microparticles in each of the sequence of digital images with said center of said microparticle”) and a structure which accomplishes the recited function.

As explained in the '994 patent specification and reflected in the claims, optical signals are collected from the microparticles and used to

³ Jeff Gelles et al., *Tracking kinesin-driven movements with nanometer-scale precision*, *Nature*, 331:450-453, 1988 (Gelles).

⁴ B.W. Hicks et al., *Tracking Movements of Lipids and Thy1 Molecules in the Plasmalemma of Living Fibroblasts by Fluorescent Video Microscopy with Nanometer Scale Precision*, *J. Membrane Biology*, 144(3):231-244, 1995 (Hicks).

⁵ W. Peter Hansen et al., *Light Scatter-Based Immunoassay Without Particle Self Aggregation*, U.S. Pat 5,589,401 (granted December 31, 1996) (Hansen).

generate a sequence of digital images. This function is performed by the imaging device [3] of claim 1. Once the optical signals are recorded in successive digital images, the [4] signal tracking means performs the function of correlating the optical signals from each of the microparticles in each of the sequence of digital images with the center of the microparticle.

Findings of Fact

[FF1]⁶

The '994 patent specification describes a "detection means" with an "important feature" of having the "ability to keep **track** of individual microparticles through multiple process steps and/or cycles." Col. 8, ll. 48-50 (emphasis added).

[FF2]

The detection means (114) is shown in Figure 1a of the patent as comprising a microscope, CCD (charge-coupled device which is capable of generating a digital image), and computer. See col. 5, ll. 7-12; col. 8, ll. 48-54.

[FF3]

In connection with the tracking, the '994 patent explains that the "detection means (114) periodically records optical characteristics of individual microparticles that provide a close approximation microparticle centers." Col. 8, ll. 51-54. This function appears to correspond to the imaging device [3] of claim 1, such as the CDD device shown in Figure 1A (FF2).

⁶ "FF" refers to a Finding of Fact.

[FF4]

Once microparticle centers are determined, the patent describes assigning pixels “for determining characteristics, e.g. intensity, of an optical signal generated at each microparticle (602).” Col. 9, ll. 6-9.

[FF5]

The patent describes a preferred embodiment in which “initial pixel is assigned which encloses the computed center of a microparticle.” Col. 9, ll. 24-26.

[FF6]

The ‘994 patent specification explains what structure performs the pixel assignment (FF4 & FF5):

After the fluorescent image is collected, the focal plane of the microscope objective is returned (814) to the microparticle focal plane, where another image is collected (816) for the purpose of computing microparticle centers as described above. **The image of microparticle centers is transferred to data server (812) where data processor (818) assigns pixels of the fluorescent image to each microparticle center, as described above.**

Col. 10, ll. 13-20 (emphasis added).

Analysis

The claimed correlation of the “the optical signals from each of the microparticles in each of the sequence of digital images with said center of said microparticle” is thus performed by the “data processor.” As the “data processor” performs the computational function of assigning pixels of the fluorescent images to the microparticle centers, it would be understood by one of ordinary skill in the art to be a component of the computer shown in Figure 1a (FF2).

In cases involving a computer-implemented invention in which the inventor has invoked means-plus-function claiming, [the Federal Circuit] has consistently required that the structure disclosed in the specification be more than simply a general purpose computer or microprocessor.

That was the point made by this court in *WMS Gaming, Inc. v. International Game Technology*, 184 F.3d 1339 (Fed. Cir. 1999). In that case, the court criticized the district court, which had determined that the structure disclosed in the specification to perform the claimed function was “an algorithm executed by a computer.” The district court erred, this court held, “by failing to limit the claim to the algorithm disclosed in the specification.” *Id.* at 1348. The rationale for that decision is equally applicable here: a general purpose computer programmed to carry out a particular algorithm creates a “new machine” because a general purpose computer “in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software.” *Id.*, quoting *In re Alappat*, 33 F.3d 1526, 1545 (Fed. Cir. 1994). The instructions of the software program in effect “create a special purpose machine for carrying out the particular algorithm.” *WMS Gaming*, 184 F.3d at 1348. Thus, in a means-plus-function claim “in which the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm.” *Id.* at 1349.

Aristocrat Technologies Australia Pty Ltd. v. International Game Technology, 521 F3d 1328, 1333 (Fed. Cir. 2008).

It is thus made clear by *Aristocrat* that when a computer-implemented invention is being claimed – as is the case here – the computer is not a general purpose one, but rather a computer programmed to perform the recited function, which in this case is “to correlate the optical signals from

each of the microparticles in each of the sequence of digital images with said center of said microparticle.” The claimed “signal tracking mean” is therefore interpreted in light of the ‘994 patent specification to require a computer, or equivalent data processing structure, which comprises software or hardware that enables it to perform the claimed correlation function of limitation [4].

The claim requires [3] an “imaging device” which “record[s]” digital images and a [4] “signal tracking means” which correlates the digital images with microparticle centers. The recordation of the image is therefore explicitly recited in the claim to be carried out separately from the subsequent correlation which is accomplished with the signal tracking means. The correlation is performed in the ‘994 patent by a process involving the assignment of pixels to the microparticle center (FF4-FF6). However, we do not limit the claimed “correlate” limitation to this pixel assignment process.

1. ANTICIPATION BY BRENNER

Claims 1-4, 6, 14-24, 26-30, 33, and 34 stand rejected under 35 U.S.C. § 102 as anticipated by Brenner. The issue is this rejection is as follows:

Does Brenner describe [4] “signal tracking means effective to correlate the optical signals from each of the microparticles in each of the sequence of digital images with said center of said microparticle”?

Findings of Fact

[FF7]

Typically, the sorted molecules are exposed to ligands for binding, e.g. in drug development, or are subjected chemical or

enzymatic processes, e.g. in polynucleotide sequencing. In both of these uses it is often desirable to simultaneously observe signals corresponding to such events or processes on large numbers of microparticles.

Brenner, p. 25, ll. 34-38

[FF8]

Preferably, whenever light-generating signals, e.g. chemiluminescent, fluorescent, or the like, are employed to detect events or processes, loaded microparticles are spread on a planar substrate, e.g. a glass slide, for examination with a scanning system The scanning system should be able to reproducibly scan the substrate and to define the positions of each microparticle in a predetermined region by way of a coordinate system. In polynucleotide sequencing applications, it is important that **the positional identification of microparticles be repeatable in successive scan steps.**

Brenner, p. 26, ll. 3-10 (emphasis added).

[FF9]

Such scanning systems may be constructed from commercially available components, e.g. x-y translation table controlled by a digital computer used with a detection system comprising one or more photomultiplier tubes, or alternatively, a CCD array, and appropriate optics, e.g. for exciting, collecting, and sorting fluorescent signals . . . **Computer software** for table translation and data collection functions can be provided by commercially available laboratory software, such as Lab Windows, available from National Instruments.

Brenner, p. 26, ll. 11-23 (emphasis added).

[FF10]

The output of the photon counters is collected by computer 304, where it can be stored, analyzed, and viewed on video 360.

Brenner, p. 26, l. 38 to p. 27, l. 1 (emphasis added).

[FF11]

The stability and reproducibility of the positional localization in scanning will determine, to a large extent, the resolution for separating closely spaced microparticles. Preferably, the scanning systems should be capable of resolving closely spaced microparticles, e.g. separated by a particle diameter or less.

Brenner, p. 27, ll. 4-7.

Discussion

The issue is this rejection is whether Brenner describes the claimed system comprising a [4] “signal tracking means effective to correlate the optical signals from each of the microparticles in each of the sequence of digital images with said center of said microparticle.” Limitation [4] appears in both independent claims 1 and 29 involved in this appeal.

Brenner describes a computer loaded with software for determining the position of microparticles and correlating these positions in successive images (FF8 & FF11). Brenner also describes detecting optical signals from the particles (FF8 & FF11) as recited in claim 1. However, the Examiner did not provide sufficient evidence that Brenner teaches a computer that is able to correlate the optical signals with the microparticle centers as required by limitation [4] of the claims.

The Examiner states that Brenner performs a correlation with microparticle centers, citing Brenner’s disclosure at page 26, lines 7-10 & 11-38; page 35, lines 23-39. RAN (“Right of Appeal Notice”) 6. We have reviewed this disclosure and find evidence that Brenner registers the positions of microparticles in an array, but none that Brenner determines the microparticle centers.

Life contends that Brenner's "two-dimensional images include positional registration information for the microparticle centers" and cites page 35, lines 23-34 for support. Life Resp't Br. 8. The most pertinent passage in this disclosure is as follows:

The avidinated slide with the attached microparticles is examined with a scanning fluorescent microscope. . . . The excitation beam and fluorescent emissions are delivered and collected respectively, through the same objective lens. . . . The computer generates a two dimensional map of the slide which registers the positions of the microparticles.

In other words, Life takes the position that because a complete scan was accomplished of the slide on which the microparticles emitting fluorescence optical signals were arrayed, Brenner would necessarily measure the optical signals of the microparticle centers. This argument is not persuasive.

The claim requires a [4] "signal tracking means . . . to correlate the optical signals from each of the microparticles in each of the sequence of digital images with said center of said microparticle." We interpreted the correlation to be accomplished separately from the recordation of the images, the latter which is carried out by the "imaging device." *See Claim interpretation*, supra at p. 8-9. Brenner's teaching that the entire slide is scanned, which might include an image of the optical signals associated with the microparticle centers, corresponds to a step accomplished by the imaging device of claim 1. However, a complete scan does not satisfy limitation [4] because limitation [4] requires a structure, such as a computer or other data processing structure, which correlates the optical signals with the microparticle centers; an image of the optical signals and microparticle

centers is insufficient because it lacks a correlation step performed by a computer.

For the foregoing reasons, we reverse the rejection of claims 1-4, 6, and 14-24, 26-30, 33, and 34 under 35 U.S.C. § 102(b) as anticipated by Brenner.

2. OBVIOUSNESS IN VIEW OF BRENNER AND SCHMIDT

Claims 7-10 and 13 stand rejected under 35 U.S.C. § 103 as obvious over Brenner in view of Schmidt.

Claim 7 is dependent on claim 1 and further recites “the system is configured to designate a first pixel for determining characteristics of an optical signal generated at a microparticle, the first pixel being correlated with the center of the microparticle.

The Examiner did not meet the burden of establishing that claim 7 would have been obvious in view of Brenner and Schmidt at the time of the invention.

Pointing to disclosure on page 979 of Schmidt, the Examiner found that Schmidt disclosed a system “configured to designate a first pixel for determining characteristics of an optical signal generated at a microparticle, the first pixel being correlated with the center of the microparticle.” RAN 11. The cited disclosure from Schmidt is as follows:

“In a few cases, the centroid of the bright portion of the DIC image was determined from the weighted pixel intensity without using cross-correlation analysis.” Schmidt, p. 979 (in section titled “Nanometer-precision Analysis of Bead Position”).

The Examiner did not provide an explanation as to how determining the centroid of the bright portion of the DIC image from “the weighted pixel intensity” corresponds to the limitation recited in claim 7.

Illumina provided a declaration by Dr. Jeff Gelles, who was a Professor of Biochemistry and Molecular Pharmacology at Brandeis University in Waltham, Massachusetts, at the time the declaration was executed. Gelles Decl. ¶ 1. Dr. Gelles testified in his written declaration that he used “imaging technologies in [his] research, including differential interference contrast microscopy and multi-wavelength single molecule fluorescence microscopy.” Gelles Decl. ¶ 5. Based on his experience and education, we conclude that Dr. Gelles is qualified to testify in this matter. Gelles Decl. ¶¶ 3-6. Dr. Gelles offered opinion testimony that he did “not understand the Schmidt reference to disclose or suggest any assignment of pixels for determining properties of optical signals (or for any other purpose) following determination of the microparticle position.” Gelles Decl. ¶ 50. Dr. Gelles’s testimony is consistent with the paucity of Schmidt’s disclosure on what is meant by “weighted pixel intensity.”

Life argues:

To the extent Patent Owner relies on the Gelles Declaration to argue that Schmidt does not contemplate ‘the designation of specific pixels for ‘determining characteristics of an optical signal generated at a microparticle’“ (PO Response to ACP, pp. 18-19 and Brief, pp. 11-12, citing Declaration at ¶¶ 48-51), that reliance is misplaced for the same reasons detailed above in Section (VII)(A)(1)(b).

Life Resp’t Br. 13.

Section (VII)(A)(1)(b) of Life’s Respondent Brief addresses the sufficiency of Dr. Gelles Declaration. Life Resp’t Br. 7-8. Life contends the

Dr. Gelles's declaration is legally and substantively deficient, and provides no analysis of Brenner to support his conclusion. *Id.* at 7.

We agree with Life that Dr. Gelles's testimony regarding claim 7 is largely opinion-based. However, we have relied on it only to the extent it is consistent with Illumina's arguments that the Examiner's case is deficient.

With respect to the assignment of pixels to microparticles, Life addresses Brenner, but not Schmidt. Life Resp't Br. 8 & 13. Life did not explain how Schmidt's disclosure described a system "configured to designate a first pixel for determining characteristics of an optical signal generated at a microparticle, the first pixel being correlated with the center of the microparticle" as recited in claim 7. Life's arguments are therefore defective for the same reason we found the Examiner's argument deficient.

Accordingly, for the foregoing reasons, we reverse the rejection of claim 7, and dependent claims 8-10 and 13.

**3 & 4. OBVIOUSNESS IN VIEW OF BRENNER AND GELLES;
BRENNER AND HICKS**

Claims 7-10 and 13 stand rejected under 35 U.S.C. § 103 as obvious over Brenner in view of Gelles. Claims 7-12 stand rejected under 35 U.S.C. § 103 as obvious over Brenner in view of Hicks.

The Examiner found that Brenner combined with Gelles or Hicks rendered the subject matter of claim 7, and dependent claims 8-10 and 13 obvious under 35 U.S.C. § 103. RAN 11. The Examiner found:

Gelles and Hicks also each teach determining the positions of microparticles on a detected image (Gelles, page 450, Figure 1 and corresponding caption; Hicks, page 233, "Microscopy" and

“Image Analysis,” and page 237, Figure 3 and corresponding caption). Gelles and Hicks therefore each teach designating a first pixel for at least determining position characteristics of an optical signal generated at a microparticle, the first pixel corresponding to (or correlated with) the center of the microparticle.

RAN 11-12.

Gelles

Gelles described the movement of beads coated with kinesin on a glass coverslip to which taxol-stabilized microtubules were adhered. Gelles, p. 450, second col., ll. 4-8. Gelles recorded a video of the movement of the beads on the glass. Gelles, p. 450, second col., second paragraph. In the description of Figure 1, Gelles disclosed the methodology to determine the position of the beads on the coverslip. It is true that Gelles describes using *pixels* to determine the position of the beads on the glass slip, but the Examiner did not provide evidence that such description was a disclosure of “designat[ing] a first pixel for determining characteristics of an optical signal generated at a microparticle, the first pixel being correlated with the center of the microparticle” as required by claim 7. As the Examiner did not meet the burden of establishing prima facie obviousness, we are compelled to reverse the rejection of independent claim 7 and dependent claims 8-10 and 13.

Hicks

Hicks tracked movement of latex microspheres (FS) on fibroblasts. Hicks, p. 231. Hicks described using pixel intensities to analyze images. *Id.*

at p. 233 (“Image Analysis”). The Examiner points to this disclosure, but fails to explain how it describes the claimed limitation to “designate a first pixel for determining characteristics of an optical signal generated at a microparticle, the first pixel being correlated with the center of the microparticle” as required by claim 7.

Dr. Gelles testified that he does “not understand Hicks to disclose or suggest a system ‘configured to designate a first pixel for determining characteristics of an optical signal generated at a microparticle’ as recited in claim 7 (as amended) of the '994 patent.” Gelles Decl. ¶ 80. Dr. Gelles supported his opinion with scientific reasoning. *Id.* at ¶¶ 74, 75, 81, and 82. For example, Dr. Gelles explained that Hicks describes “convolution,” “a mathematical function that, in essence, compares a group of pixels including and surrounding a microparticle image with a Gaussian (bell) curve. The pixels compared include both pixels with a fluorescent signal and pixels with a low (background) signal.” *Id.* at ¶ 74.

Life provides an explanation as to how Hicks is said to meet limitations of dependent claims 11 and 12. Life Resp’t Br. 14. However, claims 11 and 12 depend upon claim 7 and insufficient evidence has not been provided that the limitations of claim 7 are met by Hicks.

As the Examiner did not meet the burden of establishing prima facie obviousness, we are compelled to reverse the rejection of independent claim 7 and dependent claims 8-12.

6. OBVIOUSNESS IN VIEW OF BRENNER AND HANSEN

Claims 5 stands rejected under 35 U.S.C. § 103 as obvious in view of Brenner and Hansen. Claim 5 depends on claim 1, and further recites “wherein the coefficient of variation of the diameters of said microparticles is less than two percent.” As we reversed the rejection of claim 1, and the Examiner did not provide evidence that Hansen described the deficiencies we found in Brenner, we are compelled to reverse the rejection. See RAN 12; Life Technologies Resp’t Br. 15.

CROSS APPEAL

Life appeals the Examiner’s determination not to adopt the following rejections:

1. Rejection of claims 25, 31, and 35 under 35 U.S.C. § 102 as anticipated by Brenner.
2. Rejections of claims 29-31 and 33-35 under 35 U.S.C. § 314 as impermissibly enlarging the scope of the claims.
3. Rejection of claims 1-4 under 35 U.S.C. § 102 as anticipated by Lee.⁷
4. Rejection of claims 1, 3, and 4 under 35 U.S.C. § 102 as anticipated by Schmidt.
5. Rejection of claims 1-4 under 35 U.S.C. § 103 as obvious over Gelles.

⁷ Ann A. Lee et al. *Biaxial Strain System for Cultured Cells*, U.S. Patent 6,057,150 (granted May 2, 2000) (Lee).

6. Rejection of claim 5 under 35 U.S.C. § 103 as obvious over Lee, Gelles, and Schmidt, in view of Hansen.

7. Various rejections of claims 1-4 under 35 U.S.C. § 103. Life Appeal Br., Ex. A.

8. Rejections of claims 1-4 under 35 U.S.C. § 103 as being obvious over the Brenner, Lee, Schmidt, or Gelles reference in view of the NIH Image Manual.⁸

1. ANTICIPATION BY BRENNER

Claims 25, 31, and 35 each have the limitation that the microparticles are “closely packed.” Claim 25 depends on claim 1; claim 31 depends on claim 30, which depends on independent claim 29; claim 35 depends on claim 34, which depends on claim 33, which depends on claim 29.

Each of claims 25, 31, and 35 incorporate the limitation of a “signal tracking means effective to correlate the optical signals from each of the microparticles in each of the sequence of digital images with said center of said microparticle.” We found that Brenner does not describe this limitation. Consequently, as dependent claims 25, 31, and 35 each require this limitation, there is sufficient evidence that they are anticipated by Brenner. We thus affirm the Examiner’s decision not to adopt the anticipation rejection of claims 25, 31, and 35 over Brenner.

⁸ NIH Image Manuel, *NIH Image Version 1.58*.

2. SECTION 314 REJECTION

The Examiner did not adopt the rejection of claims 29-31 and 33-35 under 35 U.S.C. § 314 as impermissibly enlarging the scope of the '994 patent claims. Claim 29 comprises an optical train "configured to collect and focus the sequence of optical signals from the microparticles." The original claims used the language "effective to" rather than "configured to." Life contends that the recitation of "configured to" expands the scope of the '994 patent claims because

the original claim language, "effective to," could be interpreted as meaning that the claimed structure *actually accomplishes* the recited function, while the new language, "configured to," could be interpreted as meaning merely that the structure is *capable* of performing the recited function.

Life Appeal Br. 15.

We are not persuaded by Life's arguments that the claim language "configured to" recited in claim 29 is broader than the claim language in claim 1 of "effective to." In both cases, the claims are directed to systems "for detecting a sequence of optical signals from each of a plurality of microparticles during a sequence of processing steps" that comprise an "optical train." The terms "effective to" and "configured to" in each case are followed by the function that the optical train is required to perform in the claimed system. Therefore, a person of ordinary skill in the art would reasonably construe the terms equivalently to indicate that the optical train is capable of performing the recited function. A system is claimed, not a method. So it would be unreasonable to read either "effective to" or "configured to" to further mean that the function must be actually

accomplished. Consequently, we find Life's arguments to have no merit and affirm the Examiner's determination not to adopt the rejection.

3. ANTICIPATION BY LEE

The Examiner did not adopt the rejection of claims 1-4 under 35 U.S.C. § 102 as anticipated by Lee. Illumina distinguished claim 1 from Lee based on the preamble of claim 1. The Examiner adopted Illumina's interpretation. Action Closing Prosecution mailed December 15, 2010 ("ACP") at 28. We find that the Examiner erred in interpreting the claim.

Claim 1 recites in its preamble that the claimed system is "for detecting a sequence of optical signals from each of a plurality of microparticles during a sequence of processing steps." According to Life, the "sole basis for the Examiner's withdrawal of the rejection of Lee was that 'the microparticles in the system disclosed by Lee are not subject to processing steps as defined by the Bridgham ['994 patent] specification during the observance of the microparticles' as purportedly required by the preamble of claim 1." Life Appeal Br. 21. Life Technologies argues that the preamble phrase "during a sequence of processing steps" is not limiting, and there is no need for Lee to disclose it to anticipate. *Id.*

Illumina contends that the Examiner did not err in not adopting the rejection. Illumina argues:

Thus, the phrase "sequence of processing steps" [as recited in the claim preamble] is unambiguously descriptive of the "sequence of optical signals" element. (See RAN, at 13). Based on this interpretation, the Examiner correctly determined that the claimed system does not encompass any "system for detecting a sequence of optical signals from each of a plurality

of microparticles,” that may be operated “during a sequence of (generic) processing steps.” (RAN, at 13). Although the entire phrase “detecting a sequence of optical signals from each of a plurality of microparticles during a sequence of processing steps” does not appear in the body of claim 1, the elements of “the sequence of optical signals from the microparticles,” “said signals,” and “the optical signals from each of the microparticles” each refer to the optical signals that are generated during, and as a result of, the “sequence of processing steps.”

Illumina Resp’t Br. 7.

Legal Principles

“Preamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim.”

Bicon, Inc. v. Straumann Co., 441 F.3d 945, 951 (Fed. Cir. 2006).

If the body of the claim ‘sets out the complete invention,’ the preamble is not ordinarily treated as limiting the scope of the claim. *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1310 (Fed. Cir. 2002)). However, the preamble is regarded as limiting if it recites essential structure that is important to the invention or necessary to give meaning to the claim. [citations omitted]. . . When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention.” *Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003).

Id. at 952.

Issue

The issues in this rejection are thus: is the invention set forth in the body of the claim is complete or does the claimed invention require the

preamble limitation “during a sequence of processing steps” for completeness; and is the preamble limitation is merely a “purpose or intended use” of the claimed invention?

Discussion

The claimed “optical train,” “imaging device,” and “signal tracking means” each have recited functions. These components are not simply general purpose structures, but must be “effective” or have the ability to carry out the recited function. See Claim interpretation, *supra* at p. 9. With respect to the “optical train,” the claim requires it to be able “to collect and focus the sequence of optical signals from the microparticles, and to record at least one optical characteristic of each microparticle.” The “imaging device” must be able to “generate and record a sequence of digital images of the microparticles” comprising the optical signals. The “signal tracking means must “correlate the optical signals from each of the microparticles in each of the sequence of digital images with said center of said microparticle.” These functions are express limitations that constrain the “optical train,” “imaging device,” and “signal tracking means” to structures which are able to perform the recited functions. The components must therefore be capable of capturing sequences of signals and sequences of digital images.

The claim preamble that the signals and images are captured “during a sequence of processing steps” does not further limit or define the subsequently recited structures “optical train,” “imaging device,” and “signal tracking means,” but rather simply reflects the intention that the system is

used during such processing steps. The processing steps constitute an environment in which the system is capable of being used, and is intended to be used, but it does not change the structure or capability of the subsequently recited components. In fact, there is no component recited in the body of the claim which would perform the sequence of processing steps. Thus, we do not see, and Illumina has not adequately explained, how the claimed preamble is a necessary component of the claimed invention and necessary to complete the invention recited in the claim body.

In contrast, claim 29 which has similar language adds the additional limitation of “a fluidics controller effective to deliver reagents to the flow cell for a sequence of processing steps.” Absent express language in the claim, we will not read this imitation into claim 1. Life Appeal Br. 19-20.

For the foregoing reasons, we conclude that the Examiner erred in not adopting the rejection of claims 1-4 as anticipated by Lee.

4. ANTICIPATION BY SCHMIDT

Life proposed a rejection of claims 1, 3, and 4 under 35 U.S.C. § 102 as anticipated by the Schmidt reference which the Examiner initially adopted, but subsequently withdrew. ACP 31-32.

Schmidt described the movement of colloidal gold particles on cells. Schmidt, p. 977. The gold particles were coated with anti-B1 integrin antibody. *Id.* The antibody bound to integrin on the cells, attaching the colloidal gold particles to the cell surface. *Id.* “Small gold aggregates [attached to the antibody] were rapidly transported preferentially to the leading edge of the lamellipod where they resumed diffusion restricted along

the edge.” *Id.* The transport of the colloidal gold particles on the cells was tracked using video microscopy. *Id.* The Examiner found that “Schmidt does not disclose a planar array of uniformly sized spherical microparticles” as recited in independent claim 1. ACP 31-32.

Life contends that “Schmidt does disclose such a planar array in that Schmidt detects and monitors the displacements of microparticles in an array on a substantially planar surface of cultured adherent cells on a glass slide, where microbeads are placed into contact with the cells. Indeed, Schmidt *discloses two planar* arrays, one comprising cells on the glass slide and one comprising microbeads, smaller in scale than the cells.” Life Appeal Br. 22.

These arguments are not persuasive. First, Life has not provided persuasive evidence that cells are microparticles as that term would be interpreted in light of the ‘994 patent specification. Secondly, Life has not explained how colloidal particles distributed on the three-dimensional surface of cells constitutes a planar array as that term would be construed in light of the patent. Consequently, we agree with Illumina that the Examiner did not err in not adopting the rejection of claims 1, 3, and 4 as anticipated by Schmidt.

5. OBVIOUSNESS IN VIEW OF GELLES

Life proposed a rejection of claims 1-4 under 35 U.S.C. § 103 as obvious over Gelles which the Examiner initially adopted, but subsequently withdrew. ACP 36-37.

Gelles describes a system for recording, analyzing, and determining precise positional information of microscopic plastic beads (i.e.,

microparticles) on a glass coverslip (i.e., a planar array) as the microparticles, driven by kinesin, attach to and move along microtubules *in vitro* (i.e., a sequence of processing steps). Gelles, p. 450, abstract and column 2, first paragraph, through page 451, first partial paragraph; and Fig. 2).

Life contends that the Examiner did not adopt the rejection because Gelles did not subject the microparticles to processing steps and because Gelles did not disclose uniform particles, both of which the Examiner stated are required by independent claim 1. Life Appeal Br. 23; *see* ACP 36-37. Illumina contends that Gelles does not disclose a sequence of processing steps. Illumina Resp't Br. 10.

As discussed above, the preamble phrase “during a sequence of processing steps” is not limiting, and there is no need for Gelles to disclose it to anticipate or render the claim obvious. -Because the Examiner erred in interpreting the claim and Illumina has not otherwise distinguished the claim over Gelles, we find that the Examiner erred in withdrawing the rejection of claims 1-4 as obvious in view of Gelles.

6. OBVIOUSNESS REJECTIONS OVER LEE, SCHMIDT, AND GELLES IN VIEW OF HANSEN

Life proposed a rejection of claim 5 under 35 U.S.C. § 103 as obvious over Lee, Gelles, and Schmidt, in view of Hansen. Life contends the Examiner

declined to adopt obviousness rejections based on Lee, Schmidt or Gelles, in view of Hansen solely because the Examiner found that Lee, Schmidt, and Gelles each purportedly fail to anticipate

and/or render independent claim 1 obvious. *See* ACP, pp. 20-21, 31, 35-36, and 41. As demonstrated above, the Examiner should not have withdrawn the rejections of claim 1 in view of Lee, Schmidt, and Gelles. Because claim 1 is anticipated by and/or obvious over each of Lee, Schmidt, and Gelles, the Examiner also erred in failing to adopt the above-identified rejections of claim 5.

Life Appeal Br. 24.

We concluded that the Examiner erred in not adopting the rejections of the claims as anticipated by the Lee and Gelles publications. However, we concluded that the Examiner properly determined that the claims were not anticipated by Schmidt. Illumina did not dispute that Hansen in view of Lee and Gelles described or suggested the subject matter of claim 5. Illumina Resp't Br. 10. Therefore, we shall reverse the Examiner's determination not to adopt the obviousness rejection of claim 5 over Lee and Gelles in view of Hansen, but affirm as it pertains to Schmidt.

7. VARIOUS NON-ADOPTED OBVIOUSNESS REJECTIONS

Life proposed numerous rejections of claims 1-4 under 35 U.S.C. § 103 that Life contends the Examiner did not consider because it "it would be 'improper' to enter a multiple reference obviousness rejection where a single reference obviousness rejection over the same reference had already been applied." Life Appeal Br. 26. Life contends that the "Examiner's refusal to adopt those obviousness SNQs solely because an anticipation or obviousness rejection over the same reference had already been applied is not legally tenable, is contrary to the MPEP, and is in tension with the prohibition against piecemeal prosecution." *Id.*

In the Request for Reexamination, Life proposed numerous rejections under 35 U.S.C. § 103. For example Gelles was combined with each of the following: Brenner, Lee, Schmidt, Douglass, Stern, King, Luck, Sizto, DiMilla, Dow, Wernet, Wilson, Brandriss, NIH Image Manual, Brenner & Brandriss, Lee & Brandriss, Schmidt & Brandriss, or Douglas & Brandriss, in eighteen separate rejections. The Examiner indicated that the rejections raised a substantial new question of patentability. Decision Granting Inter Partes Reexamination, May 10, 2010, p. 4-6. However, in a subsequent Office Action, the Examiner did not adopt all of them because the Examiner found that Gelles already described the limitations for which the additionally secondary references were cited. Non-Final Office Action, May 10, 2010, p. 13.

We agree with the Examiner. Relying on 18 separate rejections for the same limitations, and for the same limitations already identified in the primary reference, is cumulative and unnecessarily duplicative. The limitations were addressed by the Examiner in adopted rejections, making the non-adopted rejections moot.

Moreover, had Life believed that the adopted rejections were inadequate, Life could have pointed out the differences in the proposed rejections to the Examiner, and explained why they were necessary to establish unpatentability. Under 35 U.S.C. § 314(c), inter partes reexaminations are to be conducted with “special dispatch.” Cumulative rejections add to the time it takes to conduct an appeal, and thus limiting the issues is important to comply with 35 U.S.C. § 314(c).

8. OBVIOUSNESS IN VIEW OF NIH IMAGE MANUAL

The Examiner declined to consider Requester's proposed rejections based on the NIH Image Manual because Life did not establish that it qualified as prior art against the '994 patent. ACP 42-43; RAN 15. Life Challenges this determination. Life contends:

Requester has established, at least *prima facie*, that the manual was available at the same time as the software. As explained in the previously-submitted 1995 Rasband Reference (*see* Requester's August 9, 2010 submission, p. 24), NIH Image software is accompanied by a user manual. Thus, given that the 1995 Rasband Reference explains that NIH Image software is accompanied by a user manual, the NIH Image software referenced in the 1995 Opalenik Reference would have included the associated user manual. In the absence of any evidence to the contrary, and in light of the evidentiary standard for demonstrating that a reference is prior art, Requester has adequately established that the NIH Image Manual v. 1.58 is prior art.

Life Appeal Br. 28.

Legal Principles

“Because there are many ways in which a reference may be disseminated to the interested public, ‘public accessibility’ has been called the *touchstone* in determining whether a reference constitutes a ‘printed publication’ bar under 35 U.S.C. §102(b).” *In re Hall*, 781 F.2d 897, 898-99 (Fed. Cir. 1986) (emphasis added). “A given reference is ‘publicly accessible’ upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it.” *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006).

Appeal 2012-010385
Reexamination Control No. 95/000,529
US Patent 6,831,994 B2

SRI International Inc. v. Internet Security Systems Inc., 511 F.3d 1186, 1194
(Fed. Cir. 2008).

Discussion

The Examiner did not accept Life's arguments that the NIH Image Manual was prior art because the Manual did not have publication date (Non-Final Office Action, dated May 10, 2010, p. 12). Life responded by providing a publication by Rasband and Bright (*Microbeam Analysis*, 4:137-149 (1995)) which disclosed: "NIH Image comes with many other files: a user manual 'About NIH Image [.]'" Rasband, p.137, second col, first full paragraph. However, Life did not establish the document submitted by them titled "NIH Image (Version 1.58)" is the same manual referred to by Rasband and Bright. The evidence provided by Life is insufficient to establish that NIH Image (Version 1.58) was publically accessible prior to the effective filing date of the '994 Patent.

SUMMARY

Appeal

1. The rejection of claims 1-4, 6, 14-24, 26-30, 33, and 34 as anticipated by Brenner is reversed.
2. The rejection of claims 7-10 and 13 as obvious over Brenner in view of Schmidt is reversed.
3. The rejection of claims 7-10 and 13 as obvious over Brenner in view of Gelles is reversed.

4. The rejection of claims 7-12 as obvious over Brenner in view of Hicks is reversed.

5. The rejection of claim 5 as obvious over Brenner in view of Hansen is reversed.

Cross-Appeal

1. The Examiner's determination not to adopt the rejection of claims 25, 31, and 35 under 35 U.S.C. § 102 as anticipated by Brenner is affirmed.

2. The Examiner's determination not to adopt the rejection of claims 29-31 and 33-35 under 35 U.S.C. § 314 as impermissibly enlarging the scope of the claims is affirmed.

3. The Examiner's determination not to adopt the rejection of claims 1-4 under 35 U.S.C. § 102 as anticipated by Lee is reversed.

4. The Examiner's determination not to adopt the rejection of claims 1, 3, and 4 under 35 U.S.C. § 102 as anticipated by Schmidt is affirmed.

5. The Examiner's determination not to adopt the rejection of claims 1-4 under 35 U.S.C. § 103 as obvious over Gelles is reversed.

6. The Examiner's determination not to adopt the rejection of claim 5 under 35 U.S.C. § 103 as obvious over Lee and Gelles in view of Hansen is reversed.

7. The Examiner's determination not to adopt the rejection of claim 5 under 35 U.S.C. § 103 as obvious over Lee, Gelles, and Schmidt in view of Hansen is reversed.

8. The Examiner's determination not to adopt various obviousness rejections under 35 U.S.C. § 103 is affirmed.

9. The Examiner's determination not to adopt the rejection of claims 1-4 under 35 U.S.C. § 103 as obvious over the Brenner, Lee, Schmidt, or Gelles reference in view of the NIH Image Manual is affirmed.

NEW GROUNDS OF REJECTION

37 C.F.R. § 41.77(a) states that “[t]he reversal of the examiner’s determination not to make a rejection proposed by the third party requester constitutes a decision adverse to the patentability of the claims which are subject to that proposed rejection which will be set forth in the decision of the Board of Patent Appeals and Interferences as a new ground of rejection.” Accordingly, for the reasons given above, we enter the following new grounds of rejection:

- Claims 1-4 are rejected under 35 U.S.C. § 102 as anticipated by Lee.
- Claims 1-4 are rejected under 35 U.S.C. § 103 as obvious over Gelles.
- Claim 5 is rejected under 35 U.S.C. § 103 as obvious over Lee and Gelles in view of Hansen.
- Claim 5 is rejected under 35 U.S.C. § 103 as obvious over Lee, Gelles, and Schmidt in view of Hansen

This decision contains new grounds of rejection pursuant to 37 C.F.R. § 41.77(b) which provides that “[a]ny decision which includes a new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.” Accordingly, no portion of the decision is final for purposes of judicial review. A requester may also request rehearing under 37 C.F.R. § 41.79, if appropriate, however, the Board may elect to defer issuing any decision on such request for rehearing until such time that a final decision on appeal has been issued by the Board.

For further guidance on new grounds of rejection, see 37 C.F.R. § 41.77(b)-(g). The decision may become final after it has returned to the Board. 37 C.F.R. § 41.77(f).

37 C.F.R. § 41.77(b) also provides that the Patent Owner, **WITHIN ONE MONTH FROM THE DATE OF THE DECISION**, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* The owner may file a response requesting reopening of prosecution before the examiner. Such a response must be either an amendment of the claims so rejected or new evidence relating to the claims so rejected, or both.

(2) *Request rehearing.* The owner may request that the proceeding be reheard under § 41.79 by the Board upon the same record. ...

Any request to reopen prosecution before the examiner under 37 C.F.R. § 41.77(b)(1) shall be limited in scope to the “claims so rejected.” Accordingly, a request to reopen prosecution is **limited** to issues raised by the new ground(s) of rejection entered by the Board. A request to reopen prosecution that includes issues other than those raised by the new ground(s) is unlikely to be granted. Furthermore, should the patent owner seek to substitute claims, there is a presumption that only one substitute claim would be needed to replace a cancelled claim.

A requester may file comments in reply to a patent owner response. 37 C.F.R. § 41.77(c). Requester comments under 37 C.F.R. § 41.77(c) shall be **limited** in scope to the issues raised by the Board's opinion reflecting its decision to reject the claims and the patent owner's response under paragraph 37 C.F.R. § 41.77(b)(1). A newly proposed rejection is not permitted as a matter of right. A newly proposed rejection may be appropriate if it is presented to address an amendment and/or new evidence properly submitted by the patent owner, and is presented with a brief explanation as to why the newly proposed rejection is now necessary and why it could not have been presented earlier.

Compliance with the page limits pursuant to 37 C.F.R. § 1.943(b), for all patent owner responses and requester comments, is required.

The examiner, after the Board's entry of a patent owner response and requester comments, will issue a determination under 37 C.F.R. § 41.77(d) as to whether the Board's rejection is maintained or has been overcome. The proceeding will then be returned to the Board together with any comments and reply submitted by the owner and/or requester under 37 C.F.R. § 41.77(e) for reconsideration and issuance of a new decision by the Board as provided by 37 C.F.R. § 41.77(f).

Requests for extensions of time in this *inter partes* reexamination proceeding are governed by 37 C.F.R. § 1.956. See also 37 C.F.R. § 41.79.

Appeal 2012-010385
Reexamination Control No. 95/000,529
US Patent 6,831,994 B2

REVERSED; NEW GROUNDS UNDER § 41.77(b)

Patent Owner:

REINHART BOERNER VAN DEUREN S.C.
ATTN: LINDA KASULKE, DOCKET COORDINATOR
1000 North Water Street, Suite 2100
Milwaukee, WI 53202

Third Party Requester:

ALAN HAMMOND
LIFE TECHNOLOGIES CORPORATION
ATTN: IP DEPARTMENT
5791 Van Alley Way
Carlsbad, CA 92008