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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DANA A. MARSHALL, THEODORE S. MCMINN, and DAN VADIM REGELMAN[1]

Appeal 2019-003622
Application 14/959,108
Technology Center 1600

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the Real Party in Interest as BacterioScan Ltd. App. Br. 1.

SUMMARY

Appellant files this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1–5, 11–19, and 40–48 as unpatentable under 35 U.S.C. § 103 over the combination of Praglin et al. (US 3,832,532, August 27, 1974) ("Praglin"), Feng et al. (US 8,603,769 B2, December 10, 2013) ("Feng"), and Hale, D. C., et al., *Rapid Screening for Bacteriuria by Light Scatter Photometry (Autobac): a Collaborative Study*, 13 J. CLIN. MICROBIOLOGY 147–150 (1981).

We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE and enter a NEW GROUND OF REJECTION.

NATURE OF THE CLAIMED INVENTION

Appellant's invention is directed to a method of determining the concentration of bacteria in a plurality of fluid samples by incubating the fluid samples in cuvette chambers, repeatedly transmitting an input beam through each fluid sample, and determining concentration in response to changes in a forward-scatter signal caused by the beam. Spec. ¶ 15.

REPRESENTATIVE CLAIM

Claim 1 is representative of the claims on the appeal and recites:

> 1. A method of identifying bacteria in a plurality of fluid samples, comprising:
>
> placing each of a plurality of fluid samples in one of a plurality of cuvettes, each cuvette having a first window for receiving an input beam and a second window for transmitting a forward-scatter signal indicative of the bacteria in the fluid sample;

> incubating each of the fluid samples in the plurality of cuvettes within an optical-measuring instrument that provides the input beam;
>
> passing the input beam through each of the fluid samples while the cuvette is in the optical-measuring instrument;
>
> analyzing the average of a plurality of forward-scatter signals from each of the fluid samples;
>
> for each of a plurality of fluid samples, in response to the average of a plurality of forward-scatter signals indicating the presence of bacteria in the fluid sample, continuing to incubate the fluid sample within the optical-measuring instrument to increase the concentration of the bacteria within the fluid sample;
>
> determining whether the concentration of bacteria within each of the fluid samples has reached a predetermined concentration level;
>
> removing, from the cuvette, one of the fluid samples having an increased concentration of bacteria at or over the predetermined concentration level;
>
> continuing to incubate the other fluid samples not having an increased concentration of bacteria at or over the predetermined concentration level; and
>
> placing at least a portion of the bacteria removed from the cuvette in a mass-spectrometry microbial identification device to identify the type of bacteria.

App. Br. 18.

ISSUES AND ANALYSIS

We decline to adopt the Examiner's findings of fact, reasoning, and conclusion that the appealed claims are *prima facie* obvious over the cited

prior art, and we enter a new ground of rejection. We address the arguments raised by Appellant below.

Issue 1

Appellant argues that "[n]one of the references disclose using an average of a plurality of forward scatter signals to determine the bacteria concentration." App. Br. 6.

Analysis

The Examiner finds that Praglin teaches a method for detecting bacteria from fluid samples in cuvettes including the steps of: incubating the samples in cuvettes in an incubator, placing the cuvettes into an analyzer, and transmitting an input beam through windows in the cuvettes to obtain a forward-scatter signal indicative of bacteria in the fluid sample. Final Act. 3 (citing Praglin col. 4, ll. 49–53; col. 11, ll. 35–37; col. 17–18, claim 1). The Examiner finds Praglin teaches "repeatedly passing the input beam through [] each cuvette containing the fluid sample while the cuvettes are within the [analyzer]." *Id.* (citing Praglin col. 11, ll. 28–37).

The Examiner acknowledges that Praglin does not teach "analyzing the average of a plurality of forward scatter signals from each of the samples and in response to an average of a plurality of forward scatter signals … indicative of bacteria in the fluid sample, continuing to incubate the fluid sample." Final Act. 4. The Examiner acknowledges that Praglin does not teach "determining whether the concentration of bacteria within the fluid sample has reached a predetermined concentration level[] [and] removing the fluid sample from the cuvette having an increased concentration level at or over the predetermined concentration level." *Id.*

The Examiner finds Hale teaches a method of screening fluid samples for bacterial growth in cuvettes, including the steps of: incubating the samples for predetermined intervals to increase concentration of the bacteria, analyzing the samples by light scatter, and determining whether the concentration of bacteria has reached a predetermined concentration level of $>10^5$ colony forming units ("CFU")/ml. Final Act. 5 (citing Hale p. 148, col. 1; Table 1). The Examiner finds Feng teaches a method of identifying bacteria in a fluid sample including the steps of: incubating the bacteria to increase concentration growth, "removing a portion of the fluid sample having an increased concentration of bacteria and centrifuging to create a high concentration sample for mass spectrometric identification." *Id.* (citing Feng col. 7, ll. 6–37; col 8, ll. 22–52).

The Examiner finds it would have been obvious to combine the methods of Praglin, Hale, and Feng "because this would allow one to both rapidly detect and identify bacteria in a fluid sample in one method." Final Act. 6. The Examiner finds it would have been obvious "to base the analysis of each of the repeated forward-scatter signals from each of the samples on an average thereof because this would provide a single value indicative of the state of each particular … sample which can be easily plotted." *Id.* at 7. The Examiner finds it would have been obvious "to continue to incubate the other fluid samples not having an increased concentration of bacteria at or over a predetermined concentration level, because this would allow all of the samples to reach a concentration of bacteria suitable for analysis." *Id.*

Appellant argues the Examiner "has not offered any evidence that one of skill in the art would be motivated to analyze the average of a plurality of forward scatter signals to determine bacteria concentration." App. Br. 6.

Appellant argues that "Praglin does not disclose multiple measurements of each sample." Reply Br. 2. Appellant argues that "[t]he cited section ([c]ol. 11, ll. 28-27) of Praglin actually discloses repeated measurement of samples in the context of multiple samples. (Ex. C). In other words, if there are 12 samples, the input beam is repeatedly activated 12 times to measure each sample once." *Id.* Accordingly, Appellant argues "there is no evidence based on Praglin to average the measurements of the sample to determine the concentration of that sample." *Id.*

We are persuaded by Appellant's argument. Praglin teaches placing a cuvette on the photometer carriage, moving "the cuvette **12** through the photometer analyzer **62** dwelling briefly at each chamber S for reading," and comparing the light scattering from each chamber $S_{1–12}$ to control chamber S_c. Praglin col. 11, ll. 28–37. Praglin teaches "[t]he process is repeated for each chamber until all chambers have been read and the result printed out." *Id.* at col. 11, ll. 54–56. However, we can find no evidence that Praglin teaches or suggests "repeatedly passing the input beam through each cuvette … while the cuvettes are within the [analyzer]," as described by the Examiner. Ans. 4. Although we agree with the Examiner that "the use of average values is well established in the sciences and the use thereof reduces errors," the Examiner does not explain how this generalization applies to Praglin's light scattering method. Ans. 16. Likewise, the Examiner does not explain whether calculating an average to reduce errors applies to the light scatter voltage measured by Hale. *See* Hale 148, col. 1. Because "references to 'common sense'—whether to supply a motivation to combine or a missing limitation—cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with a

limitation missing from the prior art references specified," we do not sustain the Examiner's rejection. *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016). Likewise, the prior art rejections of the dependent claims on appeal that incorporate the Examiner's analysis of Praglin fall with the rejection of the independent claims.

NEW GROUND OF REJECTION

We here enter a new ground of rejection. Independent claims 1 and 11 are rejected as unpatentable under 35 U.S.C. § 103 as being obvious over Praglin, Feng, Hale, and Weichselbaum et al. (US 8,339,601 B2, December 25, 2012) ("Weichselbaum").

In addition to the process cited by the Examiner, Hale teaches a variation of the screening procedure that "consists of an initial-base line and a 3-hr Autobac reading, leading to prompt recognition of important bacteria with minimal delay. Such positive results could then be further evaluated by direct identification and direct susceptibility testing." Hale 150. Therefore, Hale teaches removing one of the fluid samples having an increased concentration of bacteria for directed identification testing. Hale further teaches "[i]f the Autobac determination is negative after 3 h, a 5- or 6-hr reading would still be required to detect some of the slower-growing organisms." *Id*. Therefore, Hale teaches continuing to incubate the other fluid samples not having an increased concentration of bacteria at or over the predetermined concentration level.

Weichselbaum teaches a method for counting bacteria suspended in fluid by measuring intensities of light scattered by the sample. Weichselbaum col. 3, ll. 21–26. Weichselbaum teaches fluid samples of the

bacteria are filled into test cuvettes and "light scattering measurements are repeatedly carried out and processed," to obtain repeatedly received speckles images. *Id.* at col. 5, ll. 44–57. More specifically:

> Following a manual "start" command the system automatically activates the light source (when the first test cuvette of the first specimen of fluids is examined) and initiates clocks for measuring time; and repeatedly receives for a first predefined time interval T_1 a number of discrete speckles images at a predefined exposure time and repetition rate, which are collectively designated hereinafter by rates CPS_1. Then the system prompts the operator to introduce a predefined dose of the first agent in the current queue of antibiotic agents into this examined cuvette. Meanwhile the received speckles images are automatically processed for "counting bacteria" as further described.

Id. at col. 6, ll. 21–32. Weichselbaum further teaches a method for counting bacteria as follows:

> [F]irst a scattering profile is associated to an averaged derivative computed for the earlier speckles images received when examining a test cuvette. Such association is achieved for example by a common numerical fitting technique. Alternatively a number of the earliest speckles images received for a test cuvette are similarly averaged in time and or in one, or two, dimensional angular region. A scattering profile is associated to such averaged speckles images by employing common numerical fitting of curves or three-dimensional surfaces.

Id. at col. 8, ll. 4–14. Weichselbaum teaches: "[B]y employing suitably selected repetition rates and exposure times the signal to noise ratios in which the intensity of scattered light is measured are considerably improved." *Id.* at col. 12, ll. 31–34.

In summary, Weichselbaum teaches analyzing the average of a plurality of forward-scatter signals of bacteria from a plurality of fluid samples in a cuvette. Weichselbaum teaches this method improves the

signal to noise ratios in which the intensity of scattered light is measured. A person of ordinary skill in the art would have been motivated to combine the method of Weichselbaum with that of Praglin, Feng, and Hale to improve the signal to noise ratio and thus achieve more accurate results.

We have entered a new ground for only the independent claims and leave to the Examiner the evaluation of the patentability of the other claims in view of this combination, or with other possible new-found or previously cited references by identifying the claimed elements in the prior art.

CONCLUSION

The rejection of claims 1–5, 11–19, and 40–48 as unpatentable under 35 U.S.C. §103 is reversed.

We have also entered a new ground of rejection for independent claims 1 and 11 pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides that "[a] new ground of rejection . . . shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that 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). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2010).

REVERSED

37 C.F.R. § 41.50(b)

Claims Rejected	Basis	Affirmed	Reversed	New Ground
1–5, 11–19, and 40–48	§ 103 Praglin, Feng, and Hale		1–5, 11–19, and 40–48	
1–5, 11–19, and 40–48	§ 103 Praglin, Feng, Hale, and Weichselbaum			1 and 11
Overall Outcome			1–5, 11–19, and 40–48	1 and 11