

## REMARKS

The following remarks are in response to the Examiner's Office Action mailed on June 6, 2017 and Advisory Action mailed August 23, 2017.

### **I. Examiner Interview**

Applicant thanks Examiners Russell Scott Negin and Marjorie Moran for the courtesy extended during the telephonic interviews conducted on September 17, October 16, and November 1, 2017.

Discussions were held with the Examiners regarding strategies for overcoming the rejections raised under 35 USC § 101, and a proposal to amend the claims along the lines of the amendments presented herein.

### **II. Status of the Claims**

Claims 49, 81, 83, 87, and 88 are pending. Claims 3, 6-8, 10-12, 14-16, 20-21, 23-26, 30-33, 36, 40-41, 44, 46, 48-80, 84-86, and 89-92 are canceled without prejudice. Claims 1-2, 4-5, 9, 13, 17-19, 22, 27-29, 34-35, 37-39, 42-43, 45, 47, and 82 are withdrawn. Claims 49, 81, 83, 87, and 88 are amended herein. New claims 93-95 are added herein.

#### *Claim Support*

Support for the amended and new claims is found in the original claims and throughout the specification. In particular, support for the step of "measuring the cumulative intensity signal(s), thereby generating a cumulative signal measurement" as recited at step c) of independent claim 49, as amended, is provided at least at paragraphs [0134], [0135], and [0154] of the application as published.

Further, support for amended claim 81, which depends from claim 49 and recites "said hybridization probes comprise an identical fluorophore... [and] wherein said plurality of hybridization probes are specific for different polynucleotide analytes" is provided at least at section "E. Encoding Methods Using One Color and One Intensity Per Analyte but Different Intensities

Among Analytes” at paragraphs [0101]-[0105]. In particular, at paragraph [0104], the third sentence provides an exemplary description in how a single colored fluorophore and different intensities are utilized to distinguish up to 16 different analytes.

No new matter is introduced by any amendment made herein.

Upon entry of the amended claims, claims 49, 81, 83, 87, and 93-95 will be under examination. Favorable consideration of these claims is respectfully requested in light of the present amendments and the following remarks.

### **III. Claim Rejections Under 35 U.S.C. §101**

The Office had maintained the rejection of former claims 49, 51, 53, 55, 56, 75-81, 83-88, and 90-92 under 35 U.S.C. § 101, asserting that these claims were directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more. *See* Office Action at pp. 3-4. This rejection is respectfully traversed in view of the present amendments to sole pending independent claim 49, for at least the following reasons.

The 2014 USPTO interim guidance on patent subject matter eligibility, *Federal Register*, vol. 79, no. 241 (“2014 IEG”) sets out a two part test to be applied when evaluating a claim for patent eligibility. Step 1 asks whether the claim is directed to a process, machine, manufacture, or composition of matter. Independent claim 49, as amended, is directed to a “method of detecting the presence or absence of at least seven polynucleotide analytes, in any combination of presence or absence, in a single sample solution volume”. Applicant submits that this claim, as amended, is directed to a process, and is therefore satisfies Step 1 of the test set out in the 2014 IEG. Step 2A of the test asks whether the claim is directed to a law of nature, a natural phenomenon, or an abstract idea. Applicant respectfully submits that claim 49, as amended, does not recite any of these judicial exceptions, and that Step 2A of the 2014 IEG test is satisfied. Accordingly, Applicant submits that independent claim 49, as amended, is patent eligible under 35 U.S.C. § 101.

Even if the Office asserts that amended claim 49 is directed to an abstract idea, which Applicant would strongly disagree with, the claims recite “significantly more” than an abstract idea itself. As noted in the previous response filed on May 2, 2017, the Nov. 2016 Eligibility Memo

further provides guidance on how examiners should apply the second step. Specifically, the Nov. 2016 Eligibility Memo highlights that regarding *BASCOM*, “examiners should consider the additional elements in **combination**, as well as individually, when determining whether a claim as a whole amounts to significantly more, as this may be found in the nonconventional and non-generic arrangement of known, conventional elements.” (Emphasis in Original) Furthermore, the Nov. 2016 Eligibility Memo notes that “the district court erred by failing to recognize that when combined, an inventive concept may be found in the non-conventional and non-generic arrangement of the additional elements, *i.e.*, the installation of a filtering tool at a specific location, remote from the end-users, with customizable filtering features specific to each end user (note that the term ‘inventive concept’ is often used by the courts to describe additional element(s) that amount to significantly more than a judicial exception).”

**The Instant Invention Does Not Seek to Monopolize**

Lastly, Applicant does not seek to preempt others from all possible uses of analyte detection by a coding scheme. The Federal Circuit, in *McRO, Inc. v. Bandai Namco Games Am. Inc.*, opined that “[t]he preemption concern arises when the claims are not directed to a specific invention and instead improperly monopolize ‘the basic tools of scientific and technological work.’” *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1314 (Fed. Cir. 2016) (quoting *Alice*, 134 S. Ct. at 2354, in turn quoting *Myriad*, 133 S. Ct. at 2116). The *McRO* court further explains that the claims at issue were valid under § 101 because:

The specific structure of the claimed rules would prevent broad preemption of all rules-based means of automating lip synchronization unless the limits of the rules themselves are broad enough to cover all possible approaches. ... By incorporating the specific features of the rules as claim limitations, claim 1 is limited to a specific process for automatically animating characters using particular information and techniques and does not preempt approaches that use rules of a different structure or different techniques.

*Id.* at 1315-16.

Similarly, the *BASCOM* court notes that “the claims of the ’606 patent do not preempt the use of the abstract idea of filtering content on the Internet or on generic computer components performing conventional activities. The claims carve out a specific location for the filtering system

(a remote ISP server) and require the filtering system to give users the ability to customize filtering for their individual network accounts.” *BASCOM Global Internet Services v. AT&T Mobility LLC*, 827 F.3d 1350 (Fed. Cir. 2016).

Here, as with the claims in *McRO* and *BASCOM*, the instant claims do not preempt means of detecting target analytes. Instead, the instant claims are limited to a specific process of detecting the presence or absence of each analyte of a plurality of polynucleotide analytes in a single sample volume without immobilization, physical separation, or mass spectrometry.

Based on the above, Applicant respectfully submits that the instant claims are directed to patent eligible subject matter. Withdrawal of the rejection under 35 U.S.C. § 101 is respectfully requested.

#### **IV. Claim Rejections Under 35 U.S.C. §§102 and 103**

The Office had maintained the rejection to previously submitted claims 49, 51, 53, 55-56, 75-78, 80-81, 84-88, and 90-92 under pre-AIA 35 U.S.C. 102, citing a new reference, namely Lin et al. (US2013/0261019A1) (hereinafter Lin), to support the rejection. In particular, the Office asserted that Lin teaches “nondegenerate combinations of barcodes” and that the methods of Lin “do not involve immobilization of analytes, physical separation of analytes, or mass spectrometry.” See Office Action at pp. 4-7.

As set out in the MPEP, [a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. (MPEP 2131, quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “[U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.” *Net MoneyIn, Inc. v. VeriSign, Inc.*, No. 2007-1565 slip op. at 18-19 (Fed. Cir. Oct. 20, 2008).

As discussed in the interview held September 19, 2017, and as reflected in the Interview Summary dated September 22, 2017, the present amendments to sole independent claim 49, which has been amended to recite a step of measuring a cumulative intensity signal, overcome the rejections based on Lin. Lin does not teach a method for indicating the presence or absence of at

least seven polynucleotide analytes based on measurement of intensity. Instead, the crux of Lin's invention is the use of color-coded patterns deposited on a nanorod barcode probe to detect a target of interest. The instant invention utilizes intensity to detect targets of interest. Therefore, the instant invention is not anticipated by Lin for at least this reason.

Further, Applicant maintains the position set out in the previous Office Action response that the claims, as amended, are not anticipated by Lin, since Lin teaches a method which is inherently redundant, and fails to non-degenerately indicate the presence or absence of at least seven polynucleotide analytes, as recited by the presently amended independent claim 49.

In light of the above, Applicant respectfully submits that independent claims 49 and their respective dependent claims are not anticipated by Lin. Withdrawal of the rejection under pre-AIA 35 U.S.C. §102(e) is respectfully requested.

#### **V. Claim Rejections Under 35 U.S.C. §103**

The Office had rejected former claims 79 and 83 under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lin in further view of Nie et al. (US 2003/0148544 A1) (claim 79) and in view of Orpana et. Al (WO 2010/128206) (claim 83). Without admission of the propriety of this rejection and solely in the interest of expediting prosecution, Applicant has cancelled claim 79 herein, rendering the rejection of claim 79 moot.

As to the rejection of claim 83, which depends from independent claim 49, Applicant refers to the deficiencies in Lin discussed at § IV, *supra*. Applicant respectfully submits that for at least these reasons, Lin fails to teach or suggest all of the limitations of dependent claim 83. Further, the teachings of Nie and Orpana fail to remedy the deficiencies of Lin. Accordingly, Applicant submits that claim 83, as amended, is not obvious over Lin, Nie, and Orpana, either alone or in combination. Withdrawal of the rejection under pre-AIA 35 U.S.C. §103 is respectfully requested.

#### **VI. Double Patenting**

Former claims 49, 51, 53, 55, and 56 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 20-24, respectively, of U.S. Patent No. 8,838,394.

Applicant respectfully traverses the rejection at least in view of the present amendments to sole independent claim 49. Claims 20-24 of U.S. Patent No. 8,838,394 fail to teach or suggest the

elements of claim 49, as amended. In particular, the cited claims at least fail to teach or suggest steps b) and c) of the presently amended claim 49, namely:

- b) contacting said sample solution volume with the plurality of hybridization probes and exciting the hybridization probes to generate the cumulative intensity signal(s) if one or more of the at least seven polynucleotide analytes is present in the sample volume; and
- c) measuring the cumulative intensity signal(s), thereby generating a cumulative signal measurement, wherein the cumulative signal measurement non-degenerately indicates the presence or absence of the at least seven polynucleotide analytes, in any combination of presence or absence...

For at least the foregoing reasons, Applicant submits that the present rejection is rendered moot by the amendments to the claims submitted herewith.

## CONCLUSION

In light of the remarks set forth above, Applicant believes that the pending claims are under condition for allowance. Applicant respectfully solicits the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No. 38075-716.301).

Respectfully submitted,

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By: /Lee A. Johnson/  
Lee A. Johnson, Reg. No. 75,671

WILSON SONSINI GOODRICH & ROSATI  
650 Page Mill Road  
Palo Alto, CA 94304-1050  
Phone: (650) 493-9300  
Customer No. 021971