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**To:** 2014_interim_guidance; TrialsRFC2014
**Subject:** comment on the July 2015 Update: Subject Matter Eligibility

The new examples were good. However, I did not see an example directed to pure data analysis of data collected from a laboratory instrument, such as a spectrometer, mass spectrometer, DNA sequencer, etc.

I am seeing many inconsistent 101 rejections in this area.

Generally, there are two types of method claims related to instrumentation. The first type is a method for controlling the instrument. This aspect is, at least, indirectly addressed in the 2014 Guidelines in the streamlined eligibility analysis section that recites:

"As an example, a robotic arm assembly having a control system that operates using certain mathematical relationships is clearly not an attempt to tie up use of the mathematical relationships and would not require a full analysis to determine eligibility."

The second type is a method for analyzing the data produced by an instrument that is specific to that instrument. For example, a new method of analyzing mass spectra produced by a mass spectrometer. There is nothing in the Guidelines regarding this type of claim.

I found a recently patented claim directed to analyzing data from an analyzer for analyzing reagent beads that overcame a 101 rejection along these lines. Essentially, the analyzer in this case obtains light intensity values. The patent is 9,128,860 and the application number is 14/113,180.

Claim 1 of the 9,128,860 patent was rejected under 101. Claim 1 recites:

1. A method of analysing one or more reagent beads or macrobeads retained or secured in a sample well of a sample plate, said method comprising: (i) obtaining an image of the one or more reagent beads or macrobeads retained or secured in the sample well of the sample plate, said image comprising a plurality of image pixels each having an associated intensity value; (ii) distributing the intensity values or values related to said intensity values of said image pixels amongst a plurality of intensity bins and generating an histogram; (iii) fitting a curve to said histogram; (iv) comparing said curve with an idealised profile of image pixels expected to be observed if an image of a reagent bead or macrobead which was unaffected by light emanating from neighbouring reagents beads or macrobeads was analysed; (v) determining a closeness of fit between said curve and said idealised profile; (vi) discarding intensity values or values related to said intensity values from the highest intensity bin and redistributing the remaining intensity values or values related to said intensity values amongst a plurality of intensity bins and generating a further histogram, wherein said step of redistributing said remaining intensity values or values related to said intensity values comprises maintaining the number of intensity bins substantially the same and assigning a new reduced intensity range to each of the intensity bins; (vii) repeating steps (iii)-(vi) a plurality of times; (viii) determining which curve has the closest

fit with said idealised profile; and (ix) determining the intensity of said reagent bead or macrobead by summing the intensity values or values related to said intensity values which were not discarded and which were distributed amongst said plurality of intensity bins which gave the curve having the closest fit with said idealised profile.

The Applicant argued that under the streamlined eligibility analysis of the Guidelines, the claim should be allowed. An interview was then held. After the interview, the claim was allowed. The Examiner provided the following reasons.

"Regarding 35 USC 101 and in particular by analogy to the RCT example in the USPTO Guidance (see Federal Register notice titled 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 FR 74618), the claims are allowable because claim 1, steps (iv-vi) read only on embodiments which are an improvement over the art in terms of not being significantly affected by stray neighboring bead reflections (e.g. instant specification: p. 10, lines 3-7; p. 13, line 3 through p. 14, line 13; also p. 4, line 34+ and p. 5, lines 1-26 regarding the state of the field and existing problems). The discarding of certain intensity values improves the average relative luminescence (e.g. instant specification: p. 16, line 40 through p. 17, line 6), and an improved relative luminescence is equivalent to improved signal-to-noise, which condition improves accuracy and/or throughput."

My comment is this. I think the office should provide an example addressing method claims directed to pure analysis of data obtained from instrumentation, like the claim of the 9,128,860 patent. Although the prosecution history of the 9,128,860 patent is helpful, it is not clear if the claim was allowed by analogy to the RCT case, or because under the streamlined eligibility analysis the data analysis was clearly not meant to tie up the method. The Examiner seems to suggest this latter reason by writing that "steps (iv-vi) read only on embodiments which..." An office example in this area would be extremely helpful.

Thanks
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