From: David A. Gass [e-mail redacted]
Sent: Monday, March 16, 2015 10:53 PM
To: 2014_interim_guidance
Cc: Tamayo, Raul
Subject: Comments regarding 2014 Interim Guidance

Dear Ladies and Gentlemen:

Please consider the following comments as you continue to develop guidance for interpreting 35 USC §101. I am a partner with Marshall, Gerstein & Borun in Chicago with more than twenty years of experience drafting and prosecuting patent applications on behalf of biotechnology clients, and evaluating patents in biotechnology fields. The views expressed below are my own, and do not necessarily reflect the opinions of Marshall, Gerstein & Borun or any of the firm's clients.

A. Pre-emption analysis and weighing of applicant's evidence.

The Interim Guidance memo of the Patent and Trademark Office (PTO) advances a "Subject Matter Eligibility Test" by which Examiner's must evaluate whether an invention is patent-eligible. The PTO's effort to advance a one-size-fits-all, single test is understandable, but is misguided: a single "test" is unsupported by the cases that the Office purports to interpret. The Supreme Court has rejected the notion that any single, bright-line test exists for eligibility. (*See*, e.g., *Bilski v. Kappos*, characterizing the machine-or-transformation test as an important test, but rejecting the notion that it was a definitive test.) In fact, the Supreme Court in *Alice v. CLS Bank* consistently used the word "framework" to describe its stepwise analysis, avoiding the term "test." Whether or not the PTO retains its current (or a modified) "test" in its guidance, the PTO should clearly articulate that satisfaction of such "test" is not necessarily the only means for a patent applicant to demonstrate patent-eligibility.

Although the Court has rejected the notion of a definitive test, a recurring theme in the Court's patent-eligibility jurisprudence, including the *Alice* and *Mayo v. Prometheus* cases from which the Office deduces its current "test," is that a patent directed to one of the so-called "judicial exceptions" should not be granted because such a patent would inappropriately pre-empt others from using the exception *in future research and innovation*. (See, e.g., *Alice*: "We

have described the concern that drives this exclusionary principle as one of pre-emption. … '[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it,' thereby thwarting the primary object of the patent laws. [citing *Mayo*]; see U. S. Const., Art. I, §8, cl. 8 (Congress 'shall have Power . . . To promote the Progress of Science and useful Arts'). We have 'repeatedly emphasized this . . . concern that patent law not inhibit further discovery by improperly tying up the future use of' these building blocks of human ingenuity. [citing *Mayo* and *Morse*].")

The Court has acknowledged that it is not equipped to evaluation "pre-emption." (See, for example, *Mayo*: "Courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature. And so the cases have endorsed a bright-line prohibition against patenting laws of nature, mathematical formulas and the like, which serves as a somewhat more easily administered proxy for the underlying "building-block" concern.") However, the Court has not held that the PTO is institutionally ill-suited to evaluate preemption. The PTO has technically educated examiners who are trained to evaluate both scientific literature and technical evidentiary submissions from applicants. While not required, evidence from an applicant that a claim does not pre-empt all *research* uses of a "judicial exception" should be *dispositive* that the claim is patent-eligible. Examiners should be trained to evaluate "judicial exception" questions using this additional lens, even if the evidence supplied by an applicant does not fit neatly into the "framework" discussed in *Alice*, the "proxy" discussed in other Court decisions, or the "test" that the Office sets forth in its guidance memoranda. The final guidance should require a preemption analysis before concluding that a claim is ineligible, and not merely characterize preemption as a side-effect of an ineligible claim.

B. Importance of properly defining the "judicial exception," including consideration of rebuttal evidence.

Whereas the Supreme Court has repeatedly held that "Laws of nature, natural phenomena, and abstract ideas are 'the basic tools of scientific and technological work'" and that these basic tools should not be pre-empted by a patent, the Court has, nonetheless, never *defined* any of these terms. Importantly, the PTO's initial labeling of some aspect of the claim or invention as a law of nature, or natural phenomena, or abstract idea will largely drive the PTO's

ultimate conclusion with respect to eligibility, because features characterized as part of the "judicial exception" will be given no weight on the ultimate question of whether a claim as a whole is directed to a "practical application" of, or contains "significantly more" than, the judicial exception. Because of the extreme importance of this initial characterization, and the paucity of judicial guidance for making it, the Office's guidance should stress that any allegation that a "law of nature, natural phenomena, or abstract idea" is present is a finding that (a) must be supported by reasoning or evidence; and (b) is must be reconsidered in view of arguments or evidence submitted by an applicant.

Sincerely,

/David A. Gass #38,153/

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