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Client Alert: Proposed Bill Clarifies What Can Be Patented

A Congressional Subcommittee will consider new legislation that would reverse much of the Supreme Court's recent jurisprudence regarding patent eligibility and significantly improve the chances of patenting certain software and clinical diagnostics. The proposed bill expands and clarifies 35 USC § 101 by articulating exclusions to patent eligibility and constraining the analysis to be used by courts and the patent office.

Section 101 of the Patent Act presently contains only a single sentence that addresses what is eligible to be patented. Yet over the past dozen years, courts and the Patent Office have increasingly used patent eligibility as a basis for invalidating or denying a patent by creating and broadening "judicial exceptions" to eligibility, such as abstract ideas and natural phenomena. This has sown confusion about what inventions are "eligible" for patenting and discouraged many software developers and life scientists from protecting their inventions.

In the life sciences, the bill would reverse or curtail several monumental Supreme Court decisions. The 2013 *Myriad* decision ended the patenting of gene sequences and mutations, such as the BRCA genes used to assess risks of breast and ovarian cancer. The bill would undo *Myriad* by permitting isolated genes to be patented. It also would curtail the 2012 *Mayo* decision and other cases where diagnostics were found unpatentable on the ground that a correlation between a measurement and a

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Michael B. Harlin
Mike R. Turner

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patient's health was merely a natural phenomenon. Per the bill, such a process would only be ineligible if it is a mental process performed solely in the human mind or occurs in nature wholly independent of, and prior to, any human activity.

The bill also would exclude from patentability claims to processes that are "non-technological" in nature. This change would have the greatest impact on software developers, whose work often involves taking a known process and making it more efficient through the use of computer processing. Courts and the Patent Office have long applied similar boundaries based on case law, but not consistently or with statutory guidance. As a result, it has been difficult to assess eligibility of software-based claims, and many claims to "new and useful process[es]…and useful improvement[s] thereof"—the words intended to govern eligibility in the current statute—have been rejected or, after patent issuance, invalidated.

To focus Section 101 scrutiny back on overall claim eligibility, the bill would eliminate the current Patent Office and judicial practice of ignoring parts of a claim arbitrarily deemed to be insignificant pre- or post-solution activity. Instead, it requires "considering the claimed invention as a whole and without discounting or disregarding any claim element." It also mandates that eligibility must be considered separately from novelty, obviousness, and specification support, thereby preventing courts from basing eligibility decisions on alleged lack of "inventive concept." These changes would provide attorneys with concrete, statutory-based arguments to keep the eligibility question focused, while providing patent drafters with options for pursuing claims to cover subject matter that would likely be rejected under current guidelines. Generally, we believe these proposed changes would render eligibility

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determinations more straightforward and less susceptible to inconsistent judicial or administrative interpretation.

Finally, the bill includes a section that states a court may determine patent eligibility at any time and may consider limited discovery on the issue. By focusing the eligibility question and providing statutory guidelines, the bill makes it easier for courts to address eligibility with confidence, thereby allowing courts to quickly dispense with meritless limitations while allowing eligible claims to proceed.

While the bill is likely to have broad support from many stakeholders in the IP community, Congressional efforts to amend Section 101 have failed in the past, and the bill has a long path yet to becoming law. First, there will be Subcommittee hearings and potential markup before the Judiciary Committee will consider whether to present it for a full Senate vote. Then, the House must separately consider it, all as pending midterm elections will surely command the attention of Congress. Still, the repeated efforts by the IP Subcommittee Chair to push this issue forward warrants attention, and we will continue to monitor it.

If you have any questions regarding the new legislation, please contact Mike Turner, Michael Harlin, Andrew Wood, or your Neal Gerber Eisenberg attorney.

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