Comment on Patent Eligibility Jurisprudence – 35 USC § 101
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In the past ten years, the US Supreme Court and the Federal Circuit have rendered decisions in a series of patent cases that dramatically upended years of settled law. The problem was not that specific patents were invalidated, but rather that the Supreme Court ignored the existing laws and created its own new standard for patent eligibility.

The problematic decisions were all based on the interpretation of 35 USC § 101. That law states in its entirety:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

Additional laws follow this and provide limitations. For example, 35 USC § 102 requires that an invention has to be new and useful; 35 USC § 103 says that an invention can't be an obvious variation of something that already exists; and 35 USC § 112 says that a patent application can't be too vague or over-broad.

The Supreme Court could have reached their conclusion by making minor changes in the interpretation of 35 USC §102, § 103, or § 112, and that would have tightened up the requirements a bit without upsetting the apple cart, but that's not what happened.

Before 2012, subject matter eligibility was a non-issue. Decades ago, the Supreme Court had said, "anything under the sun made by man" was patentable, and broad subject matter eligibility was well-settled law. Everyone knew there were a few foreign countries that wouldn't let inventors get patents on software or on methods of treating disease, but in the US, just about anything was fair game. Occasionally patent attorneys would get clients that wanted to patent a yoga pose, a meditation mantra, or a dance move, and those were the rare sort of thing that couldn't be patented. In a series of cases starting in 2012, this changed.

- In 2012, the Court said that laws of nature are not patent eligible. (Mayo Collaborative Services v. Prometheus Labs).
- In 2013, the Court said that products of nature, such as genes, are not patent eligible (Association for Molecular Pathology v. Myriad Genetics).
- In 2014, the Court said that abstract ideas are not patent eligible (Alice Corp. v. CLS Bank).
- In 2015, the Court said that scientific discoveries are not patent eligible (Ariosa Diagnostics v. Sequenom). It is notable that the statute specifically and explicitly says that discoveries are patentable, yet the Court reached a contrary conclusion.

These decisions were all based on 35 USC § 101 and radically reinterpreted the law.

Until 2012, the idea of patenting medical breakthroughs was not particularly controversial. While it has always been the case that laws of nature, natural phenomena, and abstract ideas were not eligible for patent protection under 35 U.S.C. § 101, medical inventions were almost

never classified as mere laws of nature, but instead as patentable applications of those laws. If inventions were new and non-obvious, patent protection could be obtained.

Many medicines are derived from naturally occurring compounds and, in the past, extracts and formulations derived from plants have been patentable. (Note: Just because it is patent eligible, doesn't mean it gets a patent, it still has to be non-obvious over what was already known, and meet the requirements of 35 USC §§102, 103, and 112.)

The jurisprudence regarding eligibility is problematic because it has no foundation; the Court relied on legal justifications that it made up on its own and read into 35 USC § 101. Because the new "laws" are based entirely on recent judicial extrapolation with no textual statutory basis, the factors for determining eligibility have been inconsistent. Various "tests" have evolved, but uncertainty remains and unfair outcomes have increased.

One way the courts and the Patent Office have tried to define the law of nature rule is by saying, "If there's another way to accomplish the goal using the law of nature that isn't covered by your patent claim, then maybe it's ok." One big problem with this justification is that it puts me, as a patent attorney, in a real bind. I can think of a half-dozen ways to design around the patent claims I'm trying to get for my client, but I can't ethically give instructions on how to design around the patent.

Every invention operates in the real world and must obey the laws of physics. Clever inventions often find new ways to use laws of nature to benefit humans. Everything from a lever, to a pulley, to a lightbulb, relies on using laws of nature. So of course, the courts have had to walk that back a bit and say that if there's "something more" than the law of nature, then maybe it's ok. But what this does in practice is make patent protection uncertain.

As a practical matter, the patent examiners try to box in the invention with specific, but sometimes irrelevant, details on how the invention is made or performed. As an overly-simple example, if I was claiming a box, the examiner would want me to specify that the corners were attached with nails, then my competitor would just build it with screws or staples instead and get around the patent. In real examples, rather than nails and staples, this would entail specifying a particular laboratory method (like PCR or ELISA), and not more general claims on what is being measured and assessed. This overly limits the scope, making the client spend more money to get less protection, and makes it easier for competitors to design around a patent, thereby undermining its value. Additionally, as more steps are added, it is less likely that any single entity infringes, and divided infringement is difficult to prove, increasing litigation cost.

The Patent Office has attempted to reduce uncertainty and improve clarity with its guidelines. This has helped reduce uncertainty in most technological fields for getting a patent, but not for enforcing it. Guidance is not law. Courts give no weight to Patent Office guidance. There remains considerable uncertainty in judicial interpretation. I have seen many recently-issued patents that will likely never be enforced because the patent-holder won't risk asserting a patent if there is considerable uncertainty whether the courts might strike the claims down under § 101.

Standards for patent eligibility are not consistently applied by the courts.

One way that uncertainty could be ameliorated would be if the Patent Office were given more deference with respect to subject matter eligibility. If, once a patent issued, it was assumed to relate to eligible subject matter unless there was clear and convincing evidence to the contrary, that might mitigate some of the value in patent protection that has been undermined.

The uncertainty and changes in patentable subject matter eligibility deter investment in technologies like personalized medicine and diagnostics or prognostic innovations. (See, for example, the article: Bernard Chao and Amy Mapes, *An Early Look at Mayo's Impact on Personalized Medicine*, 2016 Patently-O Patent Law Journal 10).

While the consequences are clear, the solution is not. Rewriting the law is likely to increase uncertainty in the near term. There is a high cost to change. Changes in the law can lead to unintended consequences, some of which may not be evident for many years. The US Patent system generally does a good job of balancing competing priorities. The law on subject matter eligibility, as it was interpreted prior to 2012, is good as-written, it is the additional interpretation that is problematic. Changes to the patent laws should be narrow, targeted, and made with care.

The changes to patent eligibility have been significant and I appreciate this opportunity to provide comments. Thank you for your time and consideration of this issue.

Sincerely,

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