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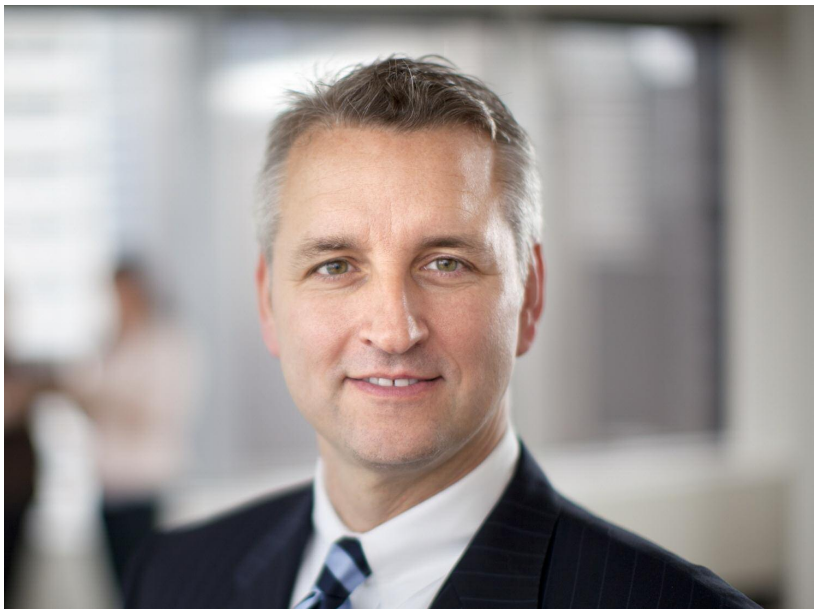

PATENTS UNDER ATTACK

The deceptively simple Section 101

By GRANTLAND DRUTCHAS

Patents appear under attack — from the Supreme Court, the Patent & Trademark Office's Patent Trial and Appeals Board and even Congress. One leading example has been the Supreme Court's increasingly stringent standards for patent eligibility under 35 U.S.C. Section 101.

The statutory language of Section 101 is deceptively simple:

"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."

Yet in a series of decisions, the Supreme Court has reiterated, and broadened, a series of "judicial exceptions" that potentially swallow this straightforward statute.

Indeed, the Supreme Court has made patent eligibility not only a question of law, ordinarily resolved by a judge, but also a "threshold" question. This has resulted in a large number of patents being invalidated on motions to dismiss at the outset of a litigation, before the parties have been able to fully develop evidentiary arguments.

Confusion over Section 101 has (hopefully) reached its zenith with the Supreme Court's decisions in *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, 566 U.S. 66, 132 S.Ct. 1289, 182 L.Ed.2d 321 (2012) (finding ineligible a diagnostic method that predicts the effectiveness of a drug dosage based on blood concentrations of certain metabolites) and *Alice Corp. Pty. Ltd. v. CLS Bank International*, 573 U.S. _, 134 S. Ct. 2347, 2354, 110 USPQ2d 1976, 1980 (2014).

In these decisions, the Supreme Court created a vague two-step decision process involving (1) whether the claims are "directed to" one of the judicial exceptions and (2) whether the claims otherwise contain an "inventive concept" sufficient to "transform" the claimed abstract idea into a patent-eligible application or was "well-understood, routine [and] conventional."

By contrast, the U.S. Court of Appeals for the Federal Circuit has attempted to bring some clarity to the Section 101 debate, and a few recent Federal Circuit decisions have thrown patent owners (for now) a lifeline. In *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018), reh'g denied, 890 F.3d 1369 (Fed. Cir. 2018), the Federal Circuit held that a patentee can avoid summary judgment or a motion to dismiss on Section 101 by raising a dispute over underlying facts.

When such factual disputes do arise, the challenger must establish those facts by "clear and convincing evidence." Further, the court appeared to limit the type of evidence that can be used to establish that a claim is ineligible: "[t]he mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine and conventional." *Id.* at 1369.

In *Aatrix Software Inc. v. Green Shades Software Inc.*, 882 F.3d 1121 (Fed. Cir. 2018), reh'g denied, 890 F.3d 1354 (Fed. Cir. 2018), the Federal Circuit held that a patentee can avoid dismissal at the motion to dismiss stage by making plausible factual allegations that support patent eligibility in its complaint — assuming they are not refuted in the patent itself.

In both of these decisions, the Federal Circuit confirmed that resolution of Section 101 issues often require resolution of factual disputes and provided a blueprint for patentees to avoid dismissal and summary judgment. Notably, neither *Berkheimer* nor *Aatrix* even mention the word "jury" much less address whether such factual disputes may, or must, be resolved by a jury.

And although Judge Jimmie V. Reyna raised the jury question in his dissent to the denial of rehearing en banc in both cases, the rest of the court was equally silent as to whether these factual disputes must be resolved by a jury. But such disputed issues of fact often require jury resolution, as they do in cases involving obviousness, under 35 U.S.C. Section 103, which is also a question of law.

In a third decision, *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117 (2018), the Federal Circuit did its best to narrowly constrain the Supreme Court's holding in *Mayo*, finding that claims directed to carrying out a dosage regimen for a drug to treat schizophrenia based on the results of genetic testing were patent eligible under Section 101.

The Federal Circuit found that, even though that treatment was dependent upon an individual's genetic makeup, the inclusion in the claims of specific treatment steps for treating a particular disease preclude them from being directed to or pre-empting an application of a law of nature.

The problems with the current state of Section 101 were highlighted by Judges Alan D. Lourie and Pauline Newman in their concurring opinions denying rehearing en banc in *Berkheimer* and *Aatrix*, who made direct appeals to Congress (or God?) to rectify it:

"I believe the law needs clarification by higher authority, perhaps by Congress, to work its way out of what so many in the innovation field consider are [Section] 101 problems. ... Section 101 issues certainly require attention beyond the power of this court."

Though I am not certain which is more of a long shot at this point — bipartisan congressional action or an act of God — this may be the only clear path. CL

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