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PATENT AND TRADEMARK LAW

Expert Analysis

New Bill Would Revise Patent Subject Matter Eligibility Framework

By **Robert L. Maier**

The issue of what subject matter should be patentable under 35 U.S.C. §101 is one that over the past decade has been rapidly evolving—and fairly controversial. The issue has been most prevalent, and most hotly contested, in two different areas of technology: biotechnology and software. It is not surprising that even the Supreme Court has struggled to define appropriate boundaries on patent subject matter eligibility—a test that can be somewhat amorphous and difficult to apply in some cases—and that the courts have asked Congress to intervene.

For the most part, Congress has thus far been silent on the issue, leaving the courts to wrestle with a challenging combination of highly complex technologies and a somewhat nebulous test.

However, a July court decision may trigger the end of Congress' silence. Specifically, the Federal Circuit in *American Axle* had previously held that a claim directed to "[a] method of manufacturing a shaft assembly of a driveline system" was ineligible for patenting under section 101. *Am. Axle & Mfg. v. Neapco Holdings*, 939 F.3d 1355 (Fed. Cir. 2019).

> Ultimately, while the bill still faces a long road ahead [...] it remains to be seen whether others in Congress believe this bill will bring the clarity that the courts have requested, or, instead, whether it largely preserves much of the complained-of uncertainty in the law.

Subsequently, the Federal Circuit denied a request to revisit that decision en banc, and, in a widely anticipated decision in June, in which the Supreme Court could have taken up the case as a vehicle for providing additional guidance on §101, the Supreme Court instead rejected certiorari—just as it had in other cases in recent years, and despite pleas for guidance from the Federal Circuit and U.S. Solicitor General.

Given the Supreme Court's most recent refusal to take up the issue, it may not be surprising that Congress has again mobilized, this time in the form of Senator Thom Tillis (R-NC) and his new proposed bill, the Patent Eligibility Restoration Act of 2022.

The Patent Eligibility Restoration Act of 2022

Senator Tillis has for years shown interest in intellectual property and patent reform, in particular directed to §101 patentable subject matter

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eligibility. During a Senate hearing in October of 2019, he explained that "[n]othing better demonstrates the madness in this area of law than the Chamberlain Group case, where the Federal Circuit found a garage door opener to be abstract." See *Chamberlain Grp. v. Techtronic Indus. Co.*, 935 F.3d 1341 (Fed. Cir. 2019).

In August of this year, Senator Tillis introduced the Patent Eligibility Restoration Act of 2022 (PERA), describing it as "legislation that will restore patent eligibility to important inventions across many fields, while also resolving legitimate concerns over the patenting of mere ideas, the mere discovery of what already exists in nature, and social and cultural content that everyone agrees is beyond the scope of the patent system." According to Senator Tillis:

> I have long said that clear, strong, and predictable patent rights are imperative to enable investments in the broad array of innovative technologies that are critical to the economic and global competitiveness of the United States, and to its national security. … Unfortunately, our current Supreme Court's patent eligibility jurisprudence is undermining American innovation and allowing foreign adversaries like China to overtake us in key technology innovations. This legislation, which is the product of almost four years of consensus driven stakeholder conversations from all interested parties, maintains the existing statutory categories of eligible subject matter, which have worked well for over two centuries, and addresses concerns regarding inappropriate eligibility constraints by enumerating a specific but extensive list of excluded subject matter. I look forward to continuing to work with all interested stakeholders on this important matter. Passing patent eligibility reform remains one of my top legislative priorities during my second term.

See Press Release, Tillis Introduces Landmark Legislation to Restore American Innovation (Aug. 3, 2022).

Impact on Patent Eligibility

The bill would amend 35 U.S.C. §101 to include express exceptions to patent eligibility, and guidance for how to analyze patent claims to determine patent eligibility, as well as a mechanism addressing related discovery in patent litigation.

The core of §101 would remain essentially the same: "(a) [w]hoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefore." The remaining subsections of the bill provide additional guidance. In particular, subsection (B) provides statutory exceptions on subject matter for which "a person may not obtain a patent:"

- "A mathematical formula, apart from a useful invention or discovery."
- "A process that (i) is non-technological economic, financial, business, social, cultural, or artistic process; (ii) is a mental process performed solely in the human mind; or (iii) occurs in nature wholly independent of, and prior to, any human activity."
- "An unmodified gene, as that gene exists in the human body"
- "An unmodified natural material, as that material exists in nature."

The exceptions track the technology areas in which these issues have most often been litigated. In particular, the first two exceptions above target patents to software inventions, and the next two focus on those in the biotechnology space.

Potential Impact on Software Inventions

The intended effects on the field of software are not clear. Critics say it does little more than codify the current confusion in the courts regarding software inventions. For example, the eligibility exceptions appear to simply shift the discussion of patent eligibility of software patents (e.g., fin-tech patents) to focus on whether or not a claim is "non-technological"—a test that itself seems fairly amorphous and perhaps difficult to apply uniformly.

Critics would also argue that the bill would do little more than codify a hybrid of the machine-or-transformation test and the "practical application" framework set out in the Supreme Court's landmark eligibility decision in *Alice*. In particular, subsection (b)(2)(A) would require that, regardless of the exceptions, "a person may obtain

a patent for a claimed invention that is a process described in such provision [(e.g., paragraph (B)(i))] *if that process is embodied in a machine or manufacture, unless that machine or manufacture is recited in a patent claim without integrating, beyond merely storing and executing, the steps of the process that the machine or manufacture perform*." (Emphasis added.)

Subsection (c) provides additional guidance. In particular, the bill would require eligibility to be determined with the following constraints:

A. by considering the claimed invention as a whole and without discounting or disregarding any claim element; and

B. without regard to:

i. the manner in which the claimed invention was made;

ii. whether a claim element is known, conventional, routine, or naturally occurring;

iii. the state of the applicable art, as of the date on which the claimed invention is invented; or

iv. any other consideration in section 102, 103, and 112.

This provision would divorce consideration of patent eligibility from the consideration of other patent validity issues that consider whether the subject matter that is "known, conventional, or routine." This language addresses the concern that has been raised that current jurisprudence conflates these §101 issues with issues of novelty or obviousness that should more properly be considered separately under §§102 and 103.

Potential Impact on Biotechnology Inventions

In the biotechnology space the bill as drafted would effectively overrule the Supreme Court's decisions in *Myriad Genetics* (2013). In *Myriad*, the Supreme Court held that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated …" The court also stated in *Myriad* that a "[g]roundbreaking, innovative, or even brilliant *discovery* does not by itself satisfy the 101 inquiry." (Emphasis added.)

Indeed, the bill's eligibility exceptions would require that "a human gene or natural material that is isolated, purified, enriched, or otherwise altered by human activity, or that is otherwise employed in a useful invention or discovery, shall not be considered to be unmodified." Thus, the bill would focus on human activity as the guiding factor for eligibility. This is consistent with the stated intent of the Senate Judiciary Subcommittee on Intellectual Property to "statutorily abrogate judicially created exceptions to patent eligible subject matter in favor of exclusive statutory categories of ineligible subject matter." See Press Release, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework.

Potential Impact on Patent Litigation

The bill also includes a provision addressing patent infringement actions, and specifically directing that "the court may consider limited discovery relevant only to [patent eligibility]" before ruling on a motion seeking to invalidate a patent under §101. This provision endorsing "limited discovery" may provide a more efficient and cost-effective avenue for addressing §101-specific discovery in connection with early case motions.

Conclusion

Ultimately, while the bill still faces a long road ahead—Senator Tillis' staffers have indicated it may take it more than two years to get to the President's desk, which itself may be an optimistic estimate—it remains to be seen whether others in Congress believe this bill will bring the clarity that the courts have requested, or, instead, whether it largely preserves much of the complained-of uncertainty in the law. At least one thing is certain, however: the software and biotech industries will be looking on with interest, and likely providing input into the legislative process in whatever ways they can.