

Loosening Patent Act's Section 101 rules would encourage more patent abuse by Big Pharma

On May 22, draft language of a bill was released that would loosen patentability rules found in Section 101 of the Patent Act, and undo almost every recent Supreme Court win aimed at reducing over patenting and exploitive uses of patent law. These changes would carry significant consequences and undo the bipartisan effort underway to fix pharma's exploitation of the patent system to extend their monopolies well past what the law intended.

What is Section 101 of the Patent Act?

United States patent law is codified in Title 35 of the United States Code, and authorized by the U.S. Constitution, in Article One, section 8, clause 8, which states:

"The Congress shall have power ... To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

A patent is a government issued instrument that gives the holder a period of 20 years to license, collect royalties, or prohibit use of the patent. The intent is to encourage inventors to make, reveal, and market their inventions by providing them legal exclusivity through a temporary government granted monopoly. However, excessive granting of patents has created system that is harmful to the public because it imposes undue restrictions on individuals and other inventors seeking to use their patent to create new and innovative goods.

However, in 1952 Congress clarified the language of limitations and exceptions in the Patent Act. One of the most important restrictions to combat abuse is Section 101 of the Patent Act. This provision states that a patent may only be issued on a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." This clarity allows for patent examiners to know which types of patents should be provided exclusive protection and which should be in the public domain. But like so many wellintended efforts by legislators to make goods available and at a low cost to the public, many have abused the system. And as such, the Supreme Court has had to weigh-in on the interpretation of 101.

Tillis/Coons legislation would undo major Supreme Court decisions to rein in patent abuse

Over the last several years, Supreme Court clearly expressed that this section prohibits patents in three key areas: laws of nature, abstract ideas, and natural phenomenon under Section 101.

Three cases in particular: *The Association for Molecular Pathology v. Myriad Genetics, Inc*, *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, and *Mayo Collaborative Sears. V. Prometheus Labs, Inc*. are the precedent examiners follow when interpreting 101. Because these cases dealt with topics including patenting human genes isolated from the rest of the genome (*Myriad*), computerized financial transactions (*Alice*), and medical diagnostic tests that correlate with adjustments of treatment (*Mayo*), companies are now unable to patent medical and scientific achievements that would benefit the public and this has opened up competition to provide better and less expensive diagnostics, cutting edge medical care, and greater certainty for the scientists and inventors to work in these fields without fear of patent infringement.



The Association for Molecular Pathology. v. Myriad Genetics

"Court's ruling rejects patent giving Myriad exclusive right to test/isolate breast and ovarian cancer genes... The ruling is expected to lower the cost of genetic testing and increase patient access to the test."

Why is Section 101 Important to Healthcare Costs?

Section 101 serves as a gatekeeper that prevents patents on laws of nature and natural phenomenon that are often at the heart of patient treatments and diagnostics. Inventors can still get patents on inventive applications of this knowledge, but they can't patent the knowledge itself. The Supreme Court famously said "to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'" The draft Section 101 bill would undo this decision and those related to it.

EXAMPLES: How Section 101 has improved medical treatment and lowered prices

- **Treating autoimmune disease** – A company was issued two patents on how to safely administer drugs to treat autoimmune disease. These patents described three steps: 1) administering the medication; 2) measuring how the drug was metabolized; and 3) using these measurements to determine if the dose is too high or too low. The Supreme Court said that the relationship between the concentration of certain metabolites in the blood and how the patient responded to the drug was an unpatentable law of nature and cancelled its monopoly. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).
- **Detecting breast and ovarian cancer** – A company was issued a patent based on a discovery of the location of two genes that, if mutated, greatly increase the risk of breast and ovarian cancer. If valid, the patents would give the company exclusive right to isolate these genes. The Supreme Court found that DNA, even in segments, is an unpatentable product of nature. This ruling is important for research and patient diagnostics, allowing competition for both. *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).
- **Diagnosing neurological and cardiovascular disorders** – Two cases involved issued patents that covered methods of diagnosing medical disorders by detecting certain antibodies or proteins. The judges found that the fact that certain biological markers can indicate disorders are unpatentable laws of nature, and allowed competition on testing for these diseases based on this information. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, No. 2018-1218, 2019 WL 1452697, at *1 (Fed. Cir. Apr. 1, 2019).
- **Assessing best treatment for cancer patients** – A patent was issued on a method of determining the best types of drugs to treat patients with lung cancer. The method was to examine a patient's genes for the presence or absence of certain nucleotides, and this measurement would help determine which cancer medications would be most effective. The court found this correlation was an unpatentable law of nature. *Esoterix Genetic Laboratories LLC v. Qiagen Inc.*, 133 F. Supp. 3d 349, 359 (D. Mass. 2015).
- **Setbacks in drug safety** – The Federal Circuit has refused to apply the Supreme Court's 101 decisions to cases involving using biological markers to provide patients with safer medication dosages, upholding these patents as valid. In one case a patent was issued to better treat schizophrenia patients by testing for a certain gene that indicates the patient is a poor metabolizer, and then administering a lower dose if the patient has that gene. Generic competition cannot enter because the FDA requires the safety provided by this testing. In another case a patent was upheld on treating renal failure with lower doses of pain medication. The patented process involved administering the drug, taking some measurements, and then changing the dose based on the measurement. *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018), petition for cert. pending, No. 18-817 and *Endo Pharms Inc. v. Teva*, ___ F.3d ___, 2019 WL 1387988 (Fed. Cir. Mar. 28, 2019).

CONCLUSION

The Tillis/Coons legislation would significantly handicap the U.S. judicial system in protecting against patent abuses by Big Pharma and lead to increased prescription drug prices and reduced access to life saving treatments and medications for patients. Congress should reject this legislation.