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Tech, Pharma Divided Over Section 101 Challenges Post-Alice

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Law360, New York (July 3, 2017, 10:34 AM EDT) -- 35 U.S.C. § 101 defines patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." Prior to 2010, courts had long recognized a number of well-settled limitations on Section 101, under which laws of nature, natural phenomena and abstract ideas are not entitled to patent protection. However, specific applications of those concepts could be protected.

The Jurisprudence

However, beginning in 2010 with Bilski and most recently in Alice, the U.S. Supreme Court has issued a number of opinions reshaping its Section 101 jurisprudence and limiting the types of inventions and discoveries that may be eligible for patent protection.

In 2010, in Bilski v. Kappos,[1] the Supreme Court found a method for hedging risk in commodities trading to be a patent-ineligible "abstract idea" under Section 101. The court reasoned that "limiting an abstract idea to one field of use or adding token postsolution components" does not make an otherwise abstract idea patentable.[2]

In 2012, in Mayo Collaborative Services v. Prometheus Laboratories Inc.,[3] the Supreme Court found a method for optimizing drug dosing based on patient metabolite levels to be a patent-ineligible "law of nature." The court held that a mere showing that a claimed invention is an application of a law of nature does not establish patentability under Section 101.[4] Rather, eligible subject matter requires that an invention include something more than "well-understood, routine, conventional activity previously engaged in by researchers in the field" and that the invention was not "purely conventional or obvious."[5]

In 2013, in Association for Molecular Pathology v. Myriad Genetics Inc.,[6] the Supreme Court found claims on isolated genes to be directed to a patent-ineligible law of nature but upheld the validity of claims on synthetically created genetic material under Section 101.[7]

In 2014, in Alice Corporation Pty. Ltd. v. CLS Bank International,[8] the Supreme Court found a method

for using a third party to mitigate settlement risk to be a patent-ineligible abstract idea. In addition, the court held that the two-step eligibility analysis from Mayo is applicable to any Section 101 analysis, not just the law of nature exception.[9]

The court's decisions from Bilski to Alice have clarified that patentability can no longer be found based only on a showing that a claimed invention is an application of a law of nature, natural phenomenon or abstract idea. Rather, to determine patent eligibility under Section 101, a court must determine first whether the claims are directed to a patent-ineligible concept and second whether the claim's elements, considered both individually and as an ordered combination, transform the nature of the claim into a patentable application. The court has not, however, provided clear guidance about how to apply its test. As a result, various judicial, administrative and industry groups have expressed conflicting opinions on the Supreme Court's patentable subject matter jurisprudence and on Section 101 itself.

Section 101 Challenges on the Rise

Since Alice, the number of invalidity challenges on Section 101 grounds has increased dramatically. District courts have invalidated at least some claims under Section 101 in more than 60 percent of opinions analyzing subject matter eligibility, and the Federal Circuit has done so in more than 90 percent of its opinions addressing the issue.[10] The Patent Trial and Appeal Board has instituted nearly 85 percent of petitions for covered business method review based in part on Section 101 grounds and invalidated at least some claims on those grounds in more than 97 percent of final written decisions analyzing subject matter eligibility.[11] The rise in invalidity challenges on subject matter grounds has polarized two of the country's most prominent industries, with the biopharmaceutical industry generally advocating and the software industry generally opposing Section 101 reform.

Biopharmaceutical Groups: More Is Better

Biopharmaceutical industry groups have warned that the Supreme Court's recent decisions on patent-eligibility law have negatively affected the pharmaceutical industry and assert that legislative reform may be necessary if existing jurisprudence persists.[12] As developing a new pharmaceutical product can require a research and development investment of 10-15 years and billions of dollars, strong patent protection allows innovator companies to recover those costs and invest in new research.[13] Biopharmaceutical industry groups argue that existing Section 101 jurisprudence disincentivizes pharmaceutical innovation by undermining innovators' ability to protect their intellectual property and recoup their R&D investments. Ben Jackson, vice president for legal affairs at Myriad Genetics, and Hans Sauer, deputy general counsel for intellectual property at the Biotechnology Industry Organization, have criticized Section 101, echoing that it has undermined U.S. pharmaceutical companies' abilities to protect their inventions and compete with foreign companies in the U.S.[14] Sauer has emphasized that when U.S. companies want to compete in other countries, they face the same patent protections they have always faced, but when those countries want to compete in the U.S., "they will have a free-for-all, and they will not face patents."[15]

Software Groups: Less Is More

By contrast, software industry groups have opposed Section 101 reform, attributing the industry's unprecedented innovation, growth and success in recent years to the Supreme Court's recent jurisprudence. According to industry groups, software companies have outperformed the rest of the market since Alice, growing more than 27 percent from 2014-2015.[16] In addition, the Bureau of Labor Statistics has projected 17 percent growth in employment for software developers from 2014-2024.[17]

In opposing reform, software industry groups urge stakeholders to consider the real-world evidence that the software industry is thriving instead of generalized arguments that assume that an industry will be harmed when fewer patents are issued.[18] Software industry groups insist that Alice and earlier precedent supply a much-needed weapon for software innovators threatened with litigation over weak patents.[19] David Jones, assistant general counsel of IP policy and lP law policy at Microsoft, has stated that he is encouraged by Alice and by the idea that under existing jurisprudence, "if you advance technology, you're not an abstract idea and vice versa."[20]

Compromise or Contention?

While the biopharmaceutical and software industries' positions are well-understood, what actions Congress may take, if any, to reform Section 101 remain unclear. Reform has the potential to fundamentally affect the way the biopharmaceutical and software industries develop and protect their products. With the biopharmaceutical industry focused on the need for broader patent protection and the software industry diametrically opposed, the only certainty is any reform efforts will be contentious.

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[1] 561 U.S. 593.

[2] Id. at 612.

[3] 566 U.S. 66 (2012).

[4] Id. at 72.

[5] Id. at 79, 82.

[6] 133 S. Ct. 2107 (2013).

[7] In its opinion, the court emphasized that considering its holding in Mayo, "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry." Id. at 2117.

[8] 134 S. Ct. 2347 (2014).

[9] Id. at 2349-50.

[10] Robert R. Sachs, Alicestorm Update For Q1 2017, BilskiBlog (Apr. 6, 2017) (available at http://www.bilskiblog.com/blog/2017/04/alicestorm-update-for-q1-2017.html) (stating that as of March 31, 2017, district courts have invalidated at least some claims under Section 101 in 237 of the 385 opinions analyzing subject matter eligibility since Alice and that the Federal Circuit has found at least some claims invalid under Section 101 in 80 of the 88 opinions analyzing subject matter eligibility since Alice).

[11] Id. (stating that as of March 31, 2017, the PTAB has instituted 129 of 152 petitions based at least in part on Section 101 grounds and invalidated at least some claims on Section 101 grounds in 87 of 89 final written decisions analyzing subject matter eligibility since Alice).

[12] Pharmaceutical Research and Manufacturers of America, Comments of the Pharmaceutical Research and Manufacturers of America Responding to the United States Patent and Trademark Office's Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility, Dkt. No. PTO-P-2016-0041, 9 (Jan. 18, 2017) (available at https://www.uspto.gov/sites/default/files/documents/RT2%20Comments%20PhRMA.pdf).

[13] Id. at 1-2.

[14] Scott Graham, At Stanford, Patent Experts Sound Off on Section 101, The Recorder (printed from Corporate Counsel) (Dec. 6, 2016) (available at http://www.corpcounsel.com/id=1202774015808/At-Stanford-Patent-Experts-Sound-Off-on-Section-101?mcode=0&curindex=0&curpage=ALL) ("Graham").

[15] Id.

[16] Electronic Frontier Foundation, Comments of the Electronic Frontier Foundation Regarding Requests for Comments Regarding Subject Matter Eligibility, Dkt. No. PTO-P-2016-0041, 2-3 (Jan. 18, 2017) (available at https://www.uspto.gov/sites/default/files/documents/RT2%20Comments%20Electronic%20Frontier%20Foundation.pdf).

[17] Id. at 3.

[18] Id. at 4.

[19] Id. at 2.

[20] Graham, supra.
