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Pharmaceutical and Software Industries at Odds on Potential Section 101 Reform

Congress and the courts may struggle to balance industries' competing interests in reforming patentable subject matter eligibility under 35 U.S.C. 101.

Key Points:

- Beginning in 2010, the United States Supreme Court issued a number of opinions interpreting the patent eligibility of various inventions under Section 101.
- In recent years, various judicial, administrative and industry groups have expressed conflicting opinions on the Supreme Court's patentable subject matter jurisprudence.
- Many biopharmaceutical interest groups advocate for reform, arguing that existing subject matter jurisprudence has weakened patent protection for brand name drugs and is detrimental to the biopharmaceutical industry.
- Groups in the software industry oppose reform, arguing that existing subject matter jurisprudence has provided them with a weapon against weak asserted patents and crediting existing case law with the industry's recent success.

In October 2016, the United States Patent and Trademark Office (USPTO) issued a request for comments regarding patentable subject matter eligibility under Section 101. Several interest groups have submitted comments in response, with associations in the pharmaceutical and life sciences industries generally advocating for revision of Section 101 and associations in the technology industries advocating against revision. Amid growing calls from a number of trade and interest groups to revise or repeal Section 101, how Congress or the courts will address the pharmaceutical and software industries' competing interests going forward remains to be seen.

Statutory Framework

Under US patent law, only certain types of inventions and discoveries are entitled to patent protection. 35 U.S.C. § 101 broadly defines patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[1] However, the Supreme Court has long recognized a number of judicially created limitations on patentable subject matter under which laws of nature, natural phenomena and abstract ideas are not entitled to patent protection.[2]

Prior to 2010, what qualified as patent-eligible subject matter had remained relatively unchanged for several decades. While patent protection was not available for laws of nature, natural phenomena or abstract ideas, protection for specific applications of those concepts was available. And Supreme Court

precedent had established that other patentability considerations, including novelty, obviousness, written description and definiteness, should be considered separately from patent eligibility under Section 101.

The Supreme Court from *Bilski* to *Alice*

Beginning in 2010, the Supreme Court issued a number of opinions interpreting the existing exemptions to patent-eligible subject matter and limiting the patent eligibility of various inventions under Section 101.

In 2010, in *Bilski v. Kappos*,[3] the Supreme Court relied on the "abstract idea" exception to Section 101 to hold that a method directed to hedging risk for commodities trading was not patent-eligible subject matter. The Court emphasized that "limiting an abstract idea to one field of use or adding token postsolution components" does not make an otherwise abstract idea patentable.[4] At the time, few realized that *Bilski* was merely the first of a number of critical Supreme Court decisions that would reshape patent eligibility under Section 101.

Then, in 2012, in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[5] the Supreme Court found that a method for optimizing dosing of a drug by measuring its metabolite levels in individual patients was ineligible subject matter under the "law of nature" exception to Section 101. In its opinion, the Court issued a new two-step test for determining whether a patent impermissibly claims a law of nature. The Court held that patentability cannot be found based only on a showing that a claimed invention is an application of a law of nature.[6] Rather, patent eligibility 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."[7] In other words, to determine patent eligibility under Section 101, a court must determine: (1) whether the claims are directed to a patent-ineligible concept, and (2) 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 did not, however, provide clear guidance on how to apply their test.

One year later, in 2013, in *Association for Molecular Pathology v. Myriad Genetics, Inc.*,[8] the Supreme Court again relied on the law of nature exception to Section 101 to hold that isolated genes, even if synthesized as DNA in a laboratory, are not patent-eligible.[9] The Supreme Court upheld the validity of the remaining claims of the challenged patents. Those claims were directed to non-naturally occurring synthetically created genetic material, which is patent-eligible subject matter under Section 101.

Then, in 2014, in *Alice Corporation Pty. Ltd. v. CLS Bank International*,[10] the Supreme Court applied the two-step eligibility analysis from *Mayo* to hold that a method for using a third party to mitigate settlement risk was patent-ineligible subject matter under the abstract idea exception to Section 101. The Court began by holding that the *Mayo* test for eligible subject matter is applicable to any Section 101 analysis, not just an analysis of the law of nature exception.[11] The Court then stated that the second step of the analysis, *i.e.*, determining the existence of "an inventive concept," requires that the claims both individually and as an ordered combination recite "significantly more than a patent upon the ineligible concept itself" and that "the mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention."[12]

From *Bilski* to *Alice*, these decisions reshaped the Supreme Court's long-standing interpretation of Section 101 and limited the types of inventions and discoveries that may be eligible for patent protection. Since 2016, the Federal Circuit has issued 33 written opinions analyzing subject matter eligibility under Section 101 and found claims eligible for patent protection in fewer than 20% of those opinions.

Positions on Reform

In the years since *Bilski*, various judicial, administrative and industry groups have expressed conflicting opinions on the Supreme Court's patentable subject matter jurisprudence and on Section 101 itself. On the one hand, some courts,[13] USPTO representatives,[14] and interest groups, including many in the biopharmaceutical industry, contend that the Supreme Court's recent jurisprudence has created uncertainty regarding the scope of patentable subject matter.[15] These groups insist that the Supreme Court's decisions have undermined the United States' ability to incentivize innovation and protect its intellectual property, particularly since many parties are bringing Section 101 challenges during early dispositive motions and before claim construction. On the other hand, groups associated with the software industry credit the Supreme Court's recent decisions on patentable subject matter with the industry's unprecedented innovation, growth and success in recent years.[16] These groups insist that *Alice* and its predecessors provide essential protection for software innovators threatened with litigation over weak patents.

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The Pharmaceutical Industry Highlights the Costs of R&D and Supports Reforming Section 101 to Strengthen Patent Protection

In response to the USPTO's request for comments, the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group composed primarily of brand-side pharmaceutical companies, submitted a number of arguments in support of revising Section 101.[18]

PhRMA recounted the importance of the biopharmaceutical industry to the US economy, stating that it supports a total of 4.4 million jobs, directly employs more than 854,000 Americans and accounts for nearly US$1.2 trillion in economic output.[19] According to PhRMA, developing a new medicine takes between 10 and 15 years with R&D investment costs averaging US$2.6 billion.[20] As a result, innovator companies in the biopharmaceutical industry rely on patents to protect their inventions and allow them to recover R&D costs and to fund new research.[21]

Regarding Section 101, PhRMA asserted that the "biopharmaceutical ecosystem has been negatively impacted by the evolution of patent subject matter eligibility law in the United States."[22] PhRMA voiced the following concerns with existing patent eligibility jurisprudence:

- The Section 101 analysis is being determined without first defining the scope of the alleged invention through proper claim construction.[23]
- Courts are impermissibly importing other patentability requirements such as novelty and obviousness into the Section 101 analysis.[24]
- Courts have arbitrarily and inconsistently applied the *Mayo* two-step framework, and as a result, it "is not providing effective protection for inventions that we, as a society, should incentivize and protect."[25]
- With respect to the biopharmaceutical field specifically, PhRMA emphasized that "all innovation in this area relates to laws of nature and natural phenomena in some way and the *Mayo* analysis sweeps too broadly and invalidates important contributions to society in this area that the patent system was designed to protect."[26]

Given its various criticisms, PhRMA concluded that courts have been unable to interpret Section 101 in a way that protects valuable life sciences inventions.[27] According to PhRMA, current Section 101 jurisprudence is "not protecting and incentivizing future innovation in the biopharmaceutical area" and is "causing the United States to fall behind its competitor countries in terms of the breadth of patent protection that is available for innovation in the biopharmaceutical area."[28] If current interpretations persist, PhRMA warned, Congressional reform may be necessary to correct Section 101.[29]

In December 2016, on the heels of the USPTO's request for comment, Stanford University hosted a public dialogue with the USPTO on existing Section 101 jurisprudence.[30] During that dialogue, a number of leaders in the pharmaceutical industry echoed PhRMA's comments on subject matter eligibility law under Section 101.[31] Ben Jackson, vice president for legal affairs at Myriad Genetics, stated that the judicially created exceptions to patent eligibility are the root of the Section 101 jurisprudence problem and that such exceptions should never have been created.[32] And Hans Sauer, deputy general counsel for intellectual property at the Biotechnology Industry Organization, warned that patent protection in the pharmaceutical industry has become less certain and less available than in other countries in which US biopharmaceutical companies compete, for example China and European countries.[33] Sauer noted that when US companies want to compete in these markets, they face the same patent protections they have always faced, but when those countries want to compete in the US, "they will have a free-for-all, and they will not face patents."[34]

For all of these reasons, groups associated with the biopharmaceutical industry generally have advocated reform or repeal of Section 101.

The Software Industry Touts *Alice* as a Potent Weapon to Fight Innovation-Stifling Litigants and Opposes Reforming Section 101

In contrast to biopharmaceutical groups, software and technology groups generally have credited current Section 101 jurisprudence with much of the industry's recent growth and innovation. In response to the USPTO's call for comments, the Electronic Frontier Foundation (EFF), which describes itself as a non-profit civil liberties group dedicated to defending individuals and new technologies from legal threats, submitted a statement opposing revising Section 101.[35]

The EFF emphasized that the performance of software companies, employment growth for software developers and R&D spending on software all show a "thriving sector."[36] According to the EFF, software companies have outperformed the rest of the market since *Alice*, growing more than 27% from 2014-2015, far outpacing all other industries in the same period.[37] In addition, the Bureau of Labor Statistics has projected 17% growth in employment for software developers from 2014-2024.[38] Directly contradicting arguments from the biopharmaceutical sector, the EFF urged stakeholders to "consider this real world evidence ahead of simplistic arguments that assume that an industry will be harmed when fewer patents are issued."[39]

Regarding Section 101, the EFF stated that under existing Supreme Court jurisprudence, "software development is booming and suggests no need for legislative meddling."[40] The EFF voiced the following arguments in support of existing patent eligibility jurisprudence.

- *Alice* provides essential protection for software innovators attacked by "weak patents."[41]
- Software depends on constant iterative improvement by which developers build on the work of others.[42]

- "Far from harming the software industry," existing subject matter eligibility law "has allowed the industry to thrive."[43] If the field is "thriving with fewer patents," the EFF posited, "there is no reason to impose more patenting upon it."[44]

Unlike their counterparts in the biopharmaceutical sector, leaders in the software and technology industry came out publicly to oppose Section 101 reform during the USPTO's December 2016 dialogue at Stanford. For example, David Jones, assistant general counsel of IP policy and IP law policy at Microsoft, 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."[45]

For all of these reasons, groups associated with the software industry have generally opposed Section 101 reform.

Conclusion

With two of the country's most powerful industries fundamentally opposed on the Supreme Court's existing subject matter jurisprudence, whether the legislature will take action to reform or repeal Section 101 remains unclear. However, clearly any reform effort may fundamentally impact the way biopharmaceutical and software companies conduct research and development, protect their intellectual property and do business. With pharmaceutical industry groups focused on the need for strong patent protections and software industry groups convinced that patents are a hindrance to innovation in their industry rather than a boon, the task of reforming Section 101 is sure to be a contentious one.

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Endnotes

[1] 35 U.S.C. § 101.

[2] *See, e.g.*, *Diamond v. Diehr,* 450 U.S. 175, 185 (1981); *Bilski v. Kappos*, 561 U.S. 593, 615-617 (2010); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852); *O'Reilly v. Morse*, 56 U.S. 62, 112–120 (1853).

[3] 561 U.S. 593.

[4] *Id*. at 612.

[5] 566 U.S. 66 (2012).

[6] *Id*. at 72.

[7] *Id*. at 79, 82.

[8] 133 S. Ct. 2107 (2013).

[9] 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.

[10] 134 S. Ct. 2347 (2014).

[11] *Id*. at 2349-50.

[12] *Id*. at 2355, 2358 (internal modifications omitted).

[13] In June 2015, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), the Federal Circuit reiterated the two-step analysis required by *Mayo* and affirmed a district court's finding invalidating a patent directed to a method for detecting paternally inherited nucleic acids under the law of nature exception to Section 101. In its opinion, the court explicitly highlighted the Supreme Court's guidance that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." *Id*. at 1379 (citing *Myriad Genetics*, 133 S. Ct. at 2117). Patentee subsequently petitioned for rehearing *en banc*. The Federal Circuit denied the petition, but while doing so, a number of justices issued concurrences expressing their concern regarding the status of Section 101 jurisprudence and the Supreme Court's two-step analysis under *Mayo*. *See, e.g.*, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. 2014-1139, 2014-1144, at *2 (Fed. Cir. Dec. 2, 2015) (order denying petition for rehearing *en banc*) (J. Dyk concurring) ("I share the concerns of some of my colleagues that a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in *Mayo*) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena."); *Ariosa Diagnostics*, 788 F.3d at 1380 (J. Linn concurring) ("In my view, the breadth of the second part of the test was unnecessary to the decision reached in *Mayo*. This case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain."); *Ariosa Diagnostics*, No. 2014-1139, 2014-1144, at *7 (J. Lourie concurring) ("[I]t is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts.").

[14] During an April 2016 Federal Circuit Judicial Conference in Washington, D.C., former USPTO director David Kappos voiced his strong criticism of Section 101 and the Supreme Court's decisions in *Mayo*, *Myriad*, and *Alice* — ultimately calling for Section 101 to be abolished. Ryan Davis, *Kappos Calls for Abolition Of Section 101 Of Patent Act*, Law360 (Apr. 12, 2016, 4:32PM EDT) (available at https://www.law360.com/articles/783604.) Kappos, who served as the director of the USPTO from 2009 to 2013, stated that the Supreme Court's decisions and the difficulty with which lower courts have had in interpreting and applying those decisions have made it too difficult to obtain patent protection on inventions in at least two key technological fields: life sciences and software. *Id*. Kappos noted that neither Europe nor Asia has a provision like Section 101 "and they seem to be doing just fine in constraining patent-eligible subject matter." *Id*. Kappos went on to state that foreign competitors "no longer have to steal U.S. technology" in the life sciences and software fields "since they can now take it for free." *Id*. Kappos suggested that instead of relying on Section 101 to ensure that patents are not allowed on fundamental concepts, courts should properly and independently apply other patentability requirements like novelty, nonobviousness and written description. *Id*.

[15] Marian Underweiser, senior counsel for IP policy and strategy at IBM, has stated that "[s]ubject matter eligibility law in the United States is broken. The Supreme Court's recent decisions in *Bilski*, *Mayo*, *Myriad* and *Alice* are the cause. The court has unapologetically refused to define the metes and bounds of its test, and it has—against the advice of the patent community, including the PTO—used 101 to do the work properly reserved for the other statutory sections [of invalidity], causing great uncertainty for both patentees and potential infringers." 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"). In addition, Michelle

Fisher, founder and CEO of Blaze Mobile, has said "[r]ight now, abstractness is basically a euphemism for broad claims. And that's not fair for people who 10 years ago saw a void in the marketplace and created a product, and wanted the product to have the broadest possible appeal to their consumer base, and patented that." *Id*.

[16] Colleen Chien, professor of law at Santa Clara University, has stated "[w]e need to be thinking not only from the perspective of an individual company and preserving a particular business model but more generally about innovation and making sure we have the correct incentives. … If our consumers can benefit from the additional competition that a lack of patent protection provides and pay lower prices here, and the innovator can still get their investments recovered by getting monopoly prices elsewhere, I don't think that's necessarily a bad deal for our consumers." *Id*. In addition, Mark Lemley, professor of law at Stanford University, has stated "[e]ven though I find Section 101 jurisprudence intellectually offensive because there doesn't seem to be a there there, the courts, I think, actually are engaging in a common law process that—with some exceptions—mostly in the software world at least gets them to the right result in particular cases. I think we're starting to see the development of a common law jurisprudence that actually does draw some distinctions that we can look to to understand what's going to be patentable and what's not." *Id*.

[17] USPTO Notice of Roundtables and Request for Comments, 81 Fed. Reg. 71485, Dkt. No. PTO-P-2016-0041) (Oct. 17, 2016).

[18] 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 (Jan. 18, 2017) (available at https://www.uspto.gov/sites/default/files/documents/RT2%20Comments%20PhRMA.pdf).

[19] *Id*.

[20] *Id*. at 1-2.

[21] *Id*. at 2.

[22] *Id*. at 5.

[23] *Id*. at 7.

[24] *Id*.

[25] *Id*.

[26] *Id*. at 8.

[27] *Id*. at 9 .

[28] *Id*. at 8.

[29] *Id*. at 9.

[30] Graham, *supra*.

[31] *Id.*

[32] *Id.*

[33] *Id*.

[34] *Id*.

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

[36] *Id*. at 1.

[37] *Id*. at 2-3.

[38] *Id*. at 3.

[39] *Id*. at 4.

[40] *Id*. at 2.

[41] *Id*. at 4.

[42] *Id*.

[43] *Id*. at 1.

[44] *Id*. at 2.

[45] Graham, *supra*.