

RULED OUT

Has The Supreme Court Set The Patent-Eligibility Bar Too High?

By Erin Coe | September 6, 2016

David Kappos knows there are times to be polite and times to be blunt. So when the former director of the U.S. Patent and Trademark Office spoke in April at the Federal Circuit Judicial Conference in Washington on one thing he would change about the patent system, he didn't hold back. A tangled knot of patent-eligibility case law is causing a wave of patent invalidations, and it's threatening to destabilize the U.S. economy, he said.

"I've tried to be the voice of reason, seeking consensus and the middle ground, but this is one of those situations where I feel someone needs to stand up and call it what it is — it's a mess," said Kappos, now a partner at Cravath Swaine & Moore LLP. "It's the worst mess I've seen in the 30 years I've been practicing law."

At the conference, he took a provocative position. He proposed abolishing Section 101 of the Patent Act, which sets limits on patent-eligible subject matter, saying that the U.S. Supreme Court's Section 101 decisions in *Mayo*, *Myriad* and *Alice* — and the way lower courts and patent examiners have interpreted

them — have made it too difficult to secure patents on biotechnology and software inventions. The high court’s decisions were aimed at barring patents on abstract ideas, natural phenomena and laws of nature, but they have been read so broadly that important inventions may no longer be patent-eligible, he said.

“If an invention doesn’t get over the 101 hurdle, it doesn’t even get to be considered [for a patent],” he said. “When you’ve got an entry-level decision that is set too high arbitrarily, and you can’t tell where the bar is but you can tell it’s a place that makes no sense, that, to me, is of great concern. ... I’m driven by a desire to see the right policy for our country’s patent system in order to incentivize the maximum amount of innovation, but I see it going in the wrong direction.”

Kappos’ bold proposition is one of many possible fixes to Section 101 that intellectual property groups are discussing, and with the Supreme Court refusing in June to hear the Sequenom Inc. case that many saw as a prime opportunity for more guidance, many experts believe greater momentum is building to address uncertainty in the patent-eligibility area through legislative channels rather than judicial ones.

However, it could take years before any changes to Section 101 would go into effect. And as thousands of U.S. patents are being invalidated, rejected and abandoned — and as jilted businesses start to shift their innovation and commercialization efforts abroad — the U.S. economy may not have much time to spare, experts say.

The Evolution of Section 101

The criticism of Section 101 of the Patent Act of 1952 isn’t focused on the statute itself, which many see as straightforward and broadly framed, but in how it’s been interpreted by the courts in recent years.

The section states: “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.”

“The statute is very plain on its face, and there are no exceptions in the statute,” said Robert Sachs, a partner at Fenwick & West LLP and operator of the Bilski Blog. “If you make something that is useful and new, you may be entitled to a patent.”



David Kappos

In drafting the Patent Act of 1952, Congress intended that anything under the sun made by human beings was patentable as long as applicants met the Section 101 standard and the other requirements of the act: that the invention was novel (Section 102), not obvious (Section 103), and contained a written description that enables a person skilled in the art to carry out the invention (Section 112), said Eric Cohen, a patent litigator at Brinks Gilson & Lione.

When the act was passed, the Supreme Court had already created several exceptions to what can be patented — a law of nature, a natural phenomenon or an abstract idea. The justices have interpreted Section 101 and its predecessors in light of those exceptions for more than 150 years, and Section 101 did not alter them. But a string of recent high court rulings on the measure has reshaped its application.

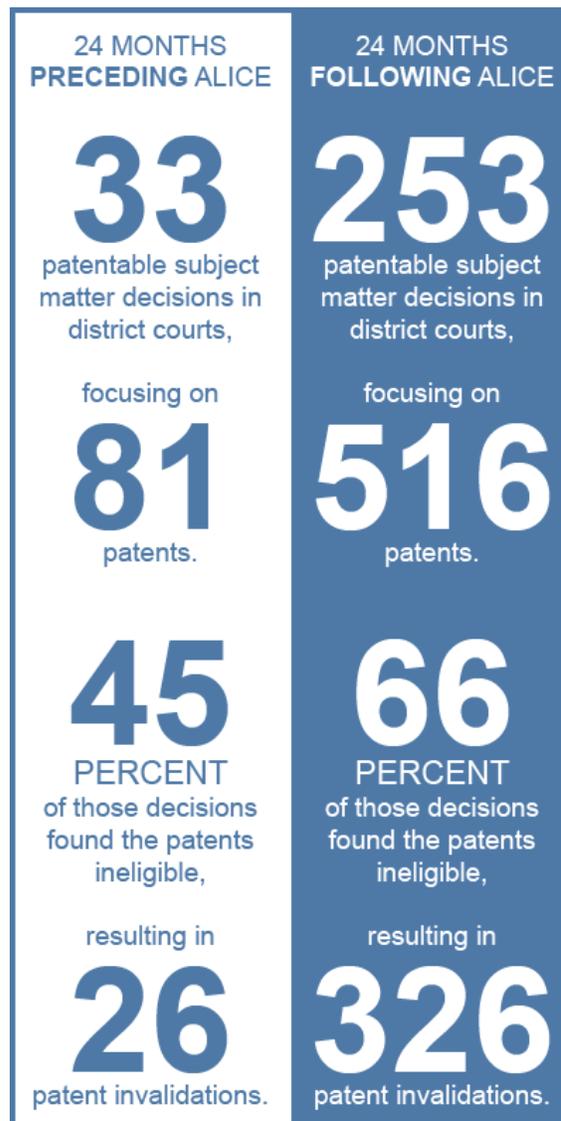
Before 2010, the provision largely had been functioning as a “coarse filter” — a first cut at excluding what were clearly unpatentable discoveries — said Adam Mossoff, a professor at Antonin Scalia Law School at George Mason University.

However, beginning with its 2010 decision in *Bilski v. Kappos* and continuing with its rulings in *Mayo Collaborative Services v. Prometheus Laboratories Inc.* in 2012, *Association for Molecular Pathology v. Myriad Genetics* in 2013, and *Alice Corp. v. CLS Bank International* in 2014, the Supreme Court demonstrated that it wanted a more muscular application of Section 101 in the patent examination process and in assessing the validity of patents that had already been issued.

In *Bilski*, the court rejected the Federal Circuit’s adoption of the machine-or-transformation test — under which an invention was patent-eligible only if it was tied to a particular machine or transformed an article into something new — as the sole test for determining whether a process was patentable. As a result, it held that an application for a method covering hedging risks in commodities trading was too abstract to be patented.

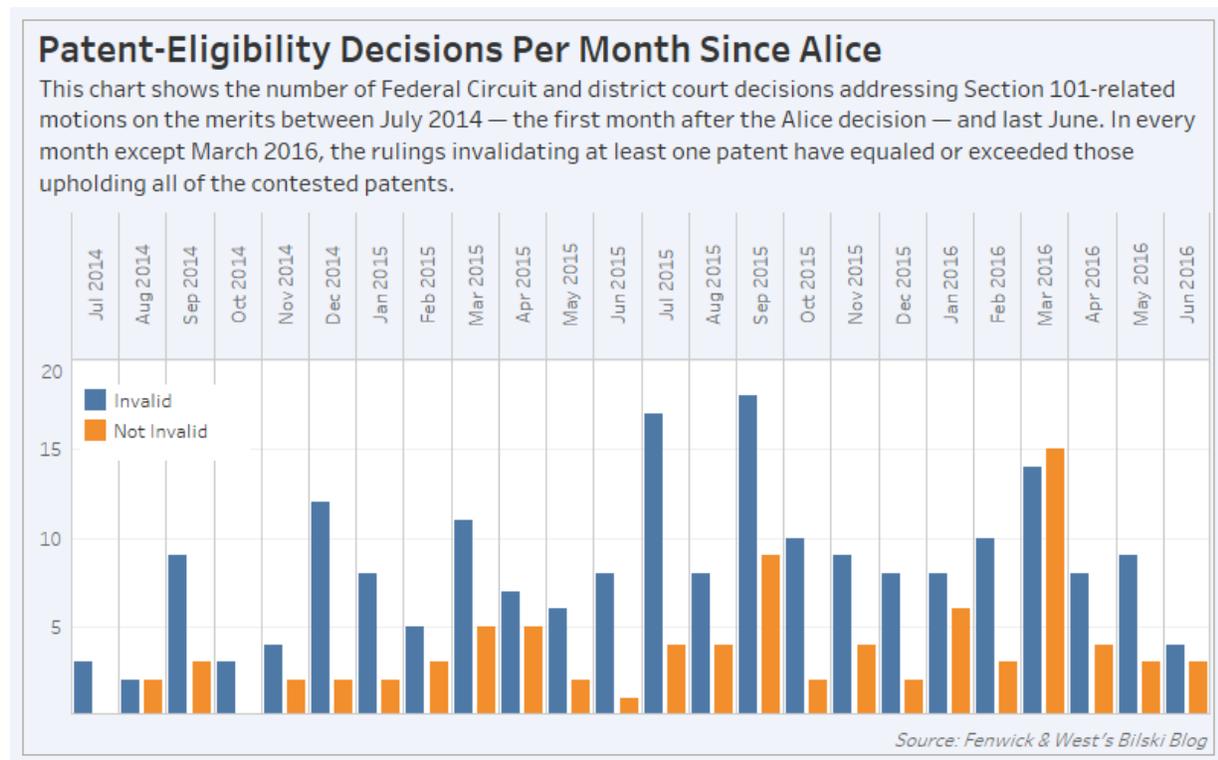
The court in *Mayo* then created a two-part test for determining whether an invention was patent-eligible: First, courts must determine whether the invention was directed to patent-ineligible subject matter like a law of nature or an abstract idea. If it was, it could be patented only if it contained other elements or a combination of elements, sometimes referred to as an “inventive concept,” so that the patent in practice amounted to significantly more than a patent of the ineligible concept itself.

At issue in the case were blood testing method patents that transformed blood taken from the body to determine the proper dosage of thiopurine drugs to treat autoimmune diseases. Applying the test, the court invalidated the patents by finding processes merely reciting laws of nature were unpatentable.



Source: *Bilski Blog*

The decision was a shock for the biotechnology industry because it cast doubt on the value of being able to diagnose diseases that were previously unknown, said Michelle Holoubek, a director at Sterne Kessler Goldstein & Fox PLLC.



In Myriad, the court concluded that the use of garden-variety methods for isolating genes tied to breast cancer was not eligible for patents. Finally, the court in Alice held that abstract ideas implemented with a computer, such as Alice’s patents claiming nothing more than the abstract concept of managing risk in financial trading using a computer, couldn’t be patented under Section 101.

The Alice decision led to the rejection of computer-implemented inventions — including systems for computer security, video streaming and photo sharing — over and over again on the basis that they cover an abstract idea, even though courts began making such decisions without defining what an abstract idea is, Holoubek said.

“This restriction of consideration as an invention before even getting to whether it is novel or nonobvious — and this cutting off of complete analysis by judges who think software-related inventions are not the type of things that should be patented — do a disservice to innovators in industries that are really leading us through the 21st century,” Holoubek said.

Part of the confusion over Section 101 stems from how differently the Supreme Court and Federal Circuit appear to view patent law. Of the 10 patent opinions it issued from its 2013 to 2015 terms that came from the Federal Circuit, the Supreme Court overturned the Federal Circuit eight times, according to Law360 data.

“The Supreme Court has been unhappy with the Federal Circuit’s approach to interpreting patent statutes and doctrines,” Mossoff said. “The byproduct of that is it’s been handing down decisions much more favorable to infringers of patents than it is to patent owners. The decisions are making it much easier to invalidate patents, harder to enforce them and harder to obtain them at the patent office.”

For some, this isn’t a bad thing. Groups including the American Civil Liberties Union argue that the high court’s take on patent eligibility is a step in the right direction. They contend that after years of Section 101 being ignored — leading to patents on things like genes and trains of thought — the justices are restoring the notion that patents shouldn’t lock up basic discoveries or laws of nature.

Others also assert that the decisions are helping companies, like those in the computer, software and communications areas, to better defend against infringement suits brought by patent assertion entities over weak patents.

“Section 101 is a way for us to get rid of junk patents that should have never issued,” said Matthew Levy, patent counsel at the Computer & Communications Industry Association. “And the advantage to using Section 101 is it can be done at an earlier stage in the game, and that saves both parties money.”

A Patent Bloodbath

The effects of the Supreme Court’s string of patentable subject matter decisions are starting to play out, as district courts, the Federal Circuit, and the Patent Trial and Appeal Board kill issued patents, the patent office rejects patent applications, and businesses abandon their U.S. applications and turn their focus abroad instead.

For example, the number of district court and Federal Circuit decisions invalidating at least one patent in suit has equaled or exceeded those upholding all of the contested patents every month since the Alice decision was issued in June 2014, except for March 2016, according to data compiled by Sachs on the Bilski Blog in June.

In the 24 months leading up to the Alice decision, there were only 33 patentable subject matter decisions in the district courts, focusing on just 81 patents. About 45 percent of those decisions found the patents ineligible, resulting in 26 patent invalidations, according to data compiled by Sachs.

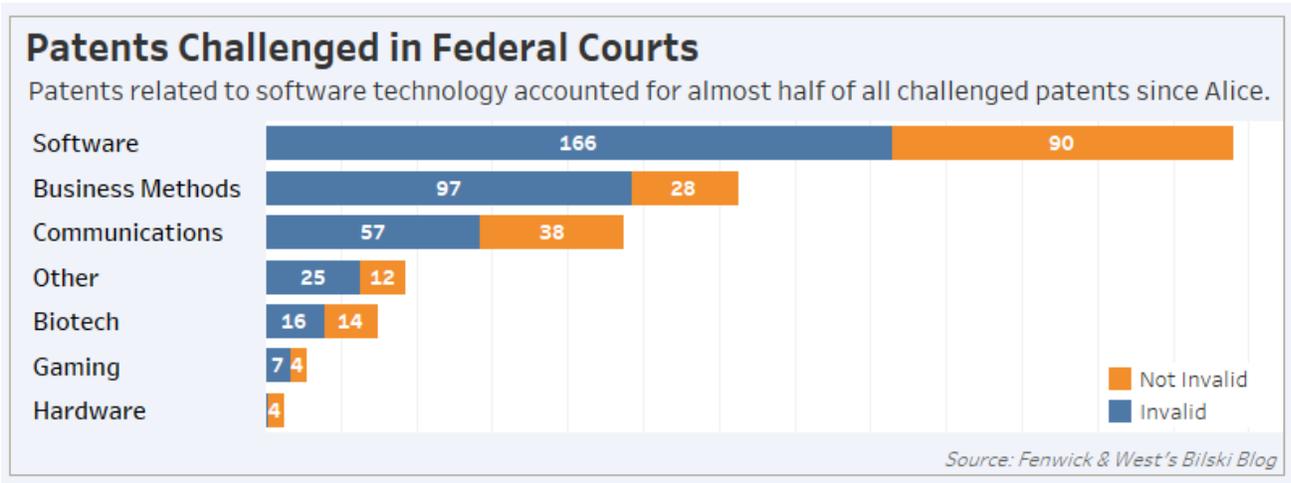
In the 24 months after Alice, the number of Section 101 motions skyrocketed, and district courts issued 253 patentable subject matter decisions — more than seven times as many — that involved challenges to 516 patents. The percentage of decisions finding ineligibility likewise jumped up to 66 percent, invalidating 326 patents, a twelve-fold increase.

The number of patent applications that have been rejected by the USPTO based on Alice is about 36,000, according to the blog. The blog also notes that the number is based on published applications, and if unpublished applications get the same treatment, the actual number of applications rejected because of Alice could be closer to 60,000.

While business method patents have been affected by the Alice decision, so have patents in all software-related fields as well as biotech patents, which have faced higher rejection rates than other technology areas, according to Sachs.

Accused infringers have made significant headway with Section 101 defense motions seeking to invalidate patents over the years, notching a success rate at district courts and the Federal Circuit of 71.7 percent last year and 70 percent this year as of June 8, according to the Bilski Blog.

These trends are due in part to a philosophical rift between the Federal Circuit and Supreme Court, experts say.



The Federal Circuit tends to craft precise standards to give its technical audience — i.e., the patent bar — predictability and guidance, but some of those rules have been viewed as overly rigid by the Supreme Court, which has a preference for multifactor tests and more flexible rules.

The high court has issued more generalized standards in its recent decisions, and at the same time a public perception has been growing that the patent system is being abused by nonpracticing entities. The outcome is that lower courts appear to be motivated to crack down on patents.

“There is a dual problem because the Supreme Court is handing down broadly framed, mushy decisions where there is no precise guidance and no one knows whether to get a patent or whether it will be deemed valid after it issues,” Mossoff said. “And on the flip side, because there’s a growing sense that the patent system is broken, there is a massive over-application of this mushy test invalidating a significant number of legitimate innovations.”

Accused infringers also have a powerful weapon at their disposal in the form of a covered business method review at the PTAB, one of the administrative proceedings implemented in 2012 under the America Invents Act allowing parties to challenge the validity of patents after they’ve been issued.

If the PTAB grants such a review, it’s an indication that a patent challenge has a reasonable likelihood of prevailing. The board has granted 83.6 percent of covered business method review petitions in which it

considered a Section 101 argument on the merits, and it has issued final decisions invalidating the patents in 96 percent of those cases, according to the Bilski Blog.

And more than 19,000 patent applications have been abandoned at least in part because of Section 101 rejections at the USPTO, including 400 applications related to cancer, 60 related to cardiovascular disease, 50 related to diabetes treatments and 35 related to stem cells, according to Sachs.

“That is a lot of jobs being lost, a lot of research not being funded and a lot of people’s investments being flushed down the toilet,” he said. “If companies can’t protect their inventions, they’re not going to do the research.”

Pockets of the biotechnology sector, such as industrial biotech, drug discovery, personalized medicine and diagnostic companies, have been hit particularly hard by patent-eligibility decisions that are being applied more broadly than expected, said Hans Sauer, deputy general counsel for intellectual property at Biotechnology Innovation Organization. And many have nothing to do with human genes or genetic testing.

“For some colleagues in advanced diagnostic and personalized medicine companies, depending on their technology, they don’t see a good way forward,” he said. “They can’t think of a promising way to get the kind of patent protection that other companies are able to get for different types of technology.”

Some big pharmaceutical companies have also grown more concerned as they face attacks on patents covering standard treatment method patents that have long existed, such as methods of cancer therapy that administer a drug to a patient who is diagnosed with carrying a certain biomarker, Sauer said.

“These patents aren’t unusual, but they are being recast in litigation by this case law, and [the decisions] are enabling those that want to attack these patents to make new arguments about why they should be invalid,” he said.

The confusion over patentable subject matter in the U.S. also has spurred companies to seek patent protection abroad, experts say. While patent applicants are facing a tougher time getting their applications through the USPTO, the patent filing rates have increased in Europe and China.

Since Alice, Kappos has identified at least 100 examples of patent applications that were rejected in the U.S. but granted in both Europe and China, which have certain technological requirements but don’t have similar Section 101 standards. Some examples include Hoffmann-La Roche Inc.’s applications for a method to identify a patient with an increased likelihood of responding to an anti-cancer therapy, Telefonaktiebolaget LM Ericsson’s application for online charging in mobile networks, and

19
THOUSAND

Number of patent applications
abandoned at least in part
due to Section 101 rejections
at the USPTO since Alice

Source: Bilski Blog as of June 8

University College Cardiff Consultants' application for methods and a kit for the prognosis of breast cancer, according to data compiled by Sachs, who collaborated with Cravath.

"It is now easier to get a patent for software-implemented and biotech inventions in China and in Europe than it is in the U.S.," Kappos said.

Not all entities have been deterred by the high court rulings on patent eligibility. While more certainty in the law would be helpful, Alexander Chai, assistant legal counsel in technology transfer at the academic nonprofit Cedars-Sinai Medical Center, said the lack of clarity will not stop it from pursuing patent rights, including in the diagnostic area.

The company's technology transfer department manages a portfolio of more than 400 technologies — such as using stem cells to repair damaged cardiac tissue and diagnostic testing for irritable bowel syndrome — that generates \$30 million in revenue annually.

Cedars-Sinai's portfolio has long included patents filed outside the U.S., and that is a strategy it plans to continue, Chai said.

"It doesn't have to do with the Section 101 decisions, but about being mindful of the global economy," he said. "In today's world, we are working in a global market, and that's more of the genesis of why we are filing internationally."

While the extent of the fallout from the Supreme Court's patentable subject matter decisions is still unclear, there is a fair amount of damage that is irrefutable, Sachs said.

"Those 19,000 patent applications that were abandoned are not coming back," he said. "They are gone ... and there is no way to undo that."

A Legislative Response?

When the Supreme Court in June declined to hear Sequenom's high-profile appeal of a decision invalidating its patent for a widely acclaimed fetal DNA test, hopes for additional clarity were dashed. The company had sought to overturn findings that its patent was ineligible because it was directed toward a natural phenomenon, and many hoped that the high court would take another crack at shedding some light on the patentable subject matter area.

Though the Federal Circuit has issued encouraging rulings for patent owners over the last few months that have helped rein in the Alice and Mayo decisions, some say they don't go far enough to clear up the murkiness of Section 101.

80
PERCENT

The Supreme Court's reversal rate of the Federal Circuit in the 10 patent cases it has heard during the three most recent terms

In May, the Federal Circuit found that Enfish LLC's database patents asserted against Microsoft Corp. didn't cover only abstract ideas, but instead claimed a patent-eligible improvement in the way computers operate. In June, it revived Bascom Global Internet Services Inc.'s suit against AT&T Corp. when it found Bascom's patent on filtering internet content improved computer functioning and was not an abstract idea.

And in July, the Federal Circuit found a district judge was wrong to hold that In Vitro Inc.'s patent was directed to a law of nature because the claimed invention actually covered a new technique for preserving liver cells. A patent didn't become ineligible simply because it involved a concept that can't be patented, the court said.

"The Federal Circuit's Enfish and other decisions have been helpful and begin to point in a constructive direction," Kappos said. "Would it be far better to see the Supreme Court help with that? Yes. Unfortunately, that is not going to happen, and we will see what the Federal Circuit can do. But it is required to follow the law from the Supreme Court, and the law [on Section 101] is such a mess."

That is why many think a legislative solution for patent eligibility may be the way to go, though discussions over a potential bill are still in the early stages.

In the last six or seven months, some members of Congress have become concerned that the patent eligibility issue is "out of control," Kappos said. Public discussions on potential legislation for Section 101 reform haven't been held yet but would likely start in the Senate Committee on the Judiciary.

One option on the table is Kappos' proposal to eliminate Section 101 altogether. Instead, other areas of the Patent Act — Section 102 related to anticipation, Section 103 related to obviousness and Section 112 related to indefiniteness — can handle the heavy lifting of filtering what should be eligible for a patent, Kappos said.

"We really can essentially get rid of Section 101," he said. "The only gap that would exist is fundamental discoveries like Einstein's Theory of Relativity or Newton's Law of Gravity, but those would already be covered as too amorphous to satisfy the requirements of Section 112."

He pointed out that the patent systems in Europe, Japan and China don't have any restriction like Section 101, and those countries are not being overwhelmed with laws of nature or abstract ideas being patented.

But many experts note that having a coarse filter as a preliminary way to weed out clearly unpatentable discoveries still serves as an important tool. Abolishing Section 101 might also be a tough proposal to sell Congress, and lawmakers may be more open to amending the provision.

Kappos said some amendment possibilities are keeping Section 101 for its statutory requirement but abolishing all judge-made law underneath it, including judicially created exceptions to what can be patentable. Another option would be mandating that an analysis of patentability start with Sections 102, 103 and 112 and end with Section 101.

“When I was running the patent office, there was an examiner who would call up applicants when there was a Section 101 problem, and if they agreed to defer the 101 rejection, he would examine cases solely on the basis of other sections,” he said. “The examiner said when applicants agreed to do the review on that basis, he never had to give a 101 rejection because all potential 101 issues were addressed through rejections using the other sections of the statute. That’s a pretty amazing test case for an examiner to demonstrate.”

Sachs said he has been working with groups at the American Bar Association, the Intellectual Property Owners Association and the American Intellectual Property Law Association on a potential amendment to Section 101. The groups are considering a variety of options. One is a proposal that would define the scope of the judicial exceptions — a law of nature, a natural phenomenon or an abstract idea — to make clear that claims that don’t fall into those categories are eligible. While this option has appeal for patent attorneys who like to define terms, gaining consensus on what the exceptions actually mean and how broad they are could prove to be difficult, Sachs said.

Another potential measure would avoid defining the judicial exceptions but would try to carve out the inventions that are ineligible, such as saying an innovation is ineligible if it can only be performed in the human mind or if it exists in nature without human involvement. This approach would avoid elaborating on the judicial exceptions, but it would still require a precise definition of carve-outs, which again could lead to disputes over the wording of the definitions and their scope.

A third option would add language that expressly bars fact-finders from considering novelty, enablement, written description or obviousness during the Section 101 review stage. This potential legislation would be fairly straightforward. Also, ideally, it would prevent examiners and courts from relying on these factors too early in the eligibility review process, while keeping them focused on the requirement of being “useful,” Sachs said.

Another possible measure would have eligibility of a claimed invention be considered based on a person with ordinary skill in the art.

“Shouldn’t the standard of eligibility be based on what someone skilled in the art thinks is an invention, rather than a lay court?” Sachs said. “When a judge looks at patent claims and has no background in the technology, they are just words and it might be easy to say something is an abstract idea. But when technologists see claims for programming a web server or biologists see claims for running equipment to isolate DNA, they’ve done these things and they have experience that binds those words to something real.”

36
THOUSAND

Number of patent applications
that have been rejected by
the USPTO based on Alice

Source: Bilski Blog as of June 8

In an article she co-wrote in the AIPLA Quarterly Journal earlier this year, Holoubek suggested an amendment that would remove inventiveness concepts from Section 101. The proposed amendment, with changes in italics, would read: “Whoever invents or discovers any new and useful *invention, which is a physically implemented process, or machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor. While the claimed invention is subject to the conditions and requirements of other sections of this title, no further conditions than novelty and usefulness of the claimed invention as a whole are required under this Section.*”

She said the tweaks focus on a “physically implemented process” to exclude innovations that shouldn’t be eligible, such as human thought, and help make clear that other conditions for patentability under Sections 102, 103 and 112 don’t need to be force-fit into Section 101.

“A legislative solution is the only realistic way that the record can be cleared,” Holoubek said. “We have a series of Supreme Court decisions, and the Supreme Court isn’t going to have a change of heart and overrule its prior cases, especially not ones so recent.

... I think a legislative approach to address this ... is what is needed to give certainty back to patent eligibility.”

Letting the Courts Handle It

Some attorneys, however, say that a legislative effort may not be needed to tackle Section 101 as the Federal Circuit starts to make some headway on clarifying the patentable subject matter area, particularly in light of its decisions in the *Enfish*, *Bascom* and *In Vitro* cases.

“What we’re seeing now is some balance being restored because the right cases are coming before the Federal Circuit,” said Bart Eppenauer, the managing partner of Shook Hardy & Bacon LLP’s Seattle office, who was the chief patent counsel at Microsoft Corp. “Each one of the Federal Circuit decisions provides meaningful guidance for inventors, patent owners and attorneys. ... As the months go by and maybe in a few more years ... we will arrive at a place that works. It’s just not the right time to pull the emergency lever.”

84
PERCENT

Rate at which PTAB has granted covered business method review petitions after considering a Section 101 argument on the merits

96
PERCENT

Rate at which PTAB has issued final decisions invalidating patents in those cases

Source: Bilski Blog through June 8

When the Alice decision first came out, the Federal Circuit issued knee-jerk rulings that invalidated patents, but as it continues to hear concerns from the patent bar that Alice and other patent eligibility decisions are unwieldy, it is trying to find a better analytical framework instead of making blanket invalidations, said Polsinelli PC shareholder Q. Todd Dickinson, who served as director of the USPTO from 1999 to 2001.

“The Federal Circuit got beat up a lot by the Supreme Court, and it got gun-shy,” he said. “But now the Federal Circuit is coming out from under the covers and trying to help the system by balancing out what Alice meant. In its *Enfish* and *Bascom* decisions, it’s reined in the scope of Alice and sharpened the analytics.”

Plus, changing patent law through the legislative process could spark conflict among key industries over what they would like to see in terms of Section 101 reform, Eppenauer said. If an outright abolition is not achievable, some industries would be willing to put constraints on other sectors, like those focused on software and computer-implemented inventions and life sciences diagnostic methods, in order to ensure their particular industry and related technologies are not so constrained.

Such industry conflicts played out in several areas during the years of legislative action leading to the America Invents Act, he said. By contrast, the judicial process is not susceptible to these types of lobbying efforts.

Getting patent legislation rolling tends to be a long and laborious endeavor, partly because of the different industry interests involved, Dickinson noted.

“For biotech companies, the patent system is invaluable to them, and they will favor patentability at every turn, while high-tech and software companies tend to want to reduce the implications on their business of others’ patents,” he said. “And then there are universities and small inventors and big manufacturers like GE and 3M with big portfolios that may want some reform, but don’t want sweeping reform.”

Conflicts over how to proceed with a legislative fix could also arise within the same industry. The tech sector, for example, might show a rift between companies that are frequently targeted by nonpracticing entities and companies like IBM, which has large patent portfolios to protect.

“Almost all of IBM’s innovation today is probably software-driven, and there is likely a concern about having a high patent-eligibility bar,” said Cohen, the Brinks Gilson attorney.

Although the Supreme Court didn’t take up the *Sequenom* case, Dickinson is hopeful that another case will soon be teed up in the Section 101 space for the high court.

“Courts are able to deal with the nuances and standards [of patent law] better,” he said. “I’m optimistic that there will be an opportunity for the Supreme Court to bring clarity to the law.”

And as the Federal Circuit and the USPTO are filling in some of the gray areas left by *Mayo* and *Alice*, lawyers are gaining some ground in securing patents, Eppenauer said.

“We’ve been able to work with our clients and follow the guidance from the USPTO as it is monitoring court decisions and putting out more guidance in how to deal with Alice,” he said. “Patent applicants that make sure their claims are directed to a practical application or a technological focus, and they describe how they achieve the end result, are having success at the patent office. As these decisions come out, there will be more and more clarity.”

Waiting Game

While there may be greater momentum behind a patent-eligibility overhaul in light of what’s at stake for industries affected by the Supreme Court’s Section 101 decisions, the question of whether companies will wait it out remains.

Significant patent reform measures like the America Invents Act took effect in 2012 after the first bills were introduced in 2006, but legislation related to Section 101 may come faster because many companies in both the biotech and high-tech industries have an interest in seeing a change.

“When the two groups are united, we could see effective lobbying for new legislation,” Mossoff said. “They both have multibillion-dollar skin in the game.”

Kappos said he is open to a number of legislative solutions that seek to make changes to Section 101.

“I’m not wedded to one particular option,” he said. “I want to see recognition that a significant new direction is needed and a move in a direction that provides much more clarity, stability and patentability for important innovations.”

Whether legislation starts ramping up next year or more court decisions come out to refine the boundaries of Section 101, companies in the meantime will be left clinging to a swinging pendulum in the patent-eligibility area.

“Right now, companies are still hopeful that things will turn around,” Holoubek said. “But the longer this [state of uncertainty] goes on, the more at risk we are of seeing decreased innovation. ... We are seeing companies looking to options outside the U.S. and giving up enforcement in the U.S. to proceed in Europe, which is now more favorable to software patents. Once they shift, it will be difficult to change their course.”

Erin Coe is a feature reporter for Law360.