Answers of Alex H. Moss to Written Questions from Senator Richard Blumenthal
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1. Striking the appropriate balance between encouraging innovation and protecting consumers is a key goal of our patent system.

    a. **What impact will broadening the subject matter that can be patented have on industry?**

Expanding the scope on patent-eligible subject matter will negatively impact on industries' ability to support innovation and market entry, especially by small businesses. As a result, promoting the proliferation of patents in high tech industries will promote the concentration of market power. Only large incumbents will be able to obtain and wield vast portfolios of broadly-drawn patents in offensive or defensive litigation. That is because only well financed corporations can afford armies of patent agents and patent lawyers to obtain and leverage large numbers of patents.

Government sanctioned monopolies in intellectual property should serve one purpose, which is to expand the scope of practical knowledge available to the public. The bargain the Science and Progress Clause gives inventors is an exchange of monopoly power through a patent for their invention to encourage them to develop advances that go beyond what is already available to the public. Exclusive rights to monetize are supposed to drive more inventors to develop *new* inventions, not to claim basic ideas and products of nature and as their own work. The Supreme Court, through its *Alice v CLS Bank* decision and those on which it relies, has repeatedly held that Section 101's limitations on patent-eligible subject matter are necessary to ensure the patent system promotes more innovation than it deters.

Innovation depends the viability of new approaches being able to enter an industry's marketplace. Often these new approaches are simply just derivative works of prior ideas and not entirely new inventions. However, were Congress to expand the scope of eligible patent subject matter, it risks giving patent holders control over more than what they have actually contributed through their invention. This larger reach will stifle new approaches from taking root as existing patent holders will have the capacity to rent seek and exploit others within their industry sector. Innovators, unable to put off expensive and unproductive litigation, will either be forced to accept greater costs to compensate rent seekers or they simply withhold their innovation from the marketplace in general. The end result being the sector as a whole becoming less innovative.

Market entry is dependent on generally two core factors. The upfront costs of starting a business and the ongoing costs of sustaining and growing the business. The upfront costs of entering an industry can be a barrier when it is high as only well capitalized entities would be able to begin their participation, which reduces the number of competitors that can enter and the number of incumbents. The ongoing costs of sustaining and growing a business is linked closely to liability

where the reach of patents plays a critical role. Should Congress expand patent law in such a way as to raise the number of instances a patent dispute will occur, it will also ensure that fewer small businesses and new competitors can exist. This is a core reason why EFF launched its *Saved by Alice* project, to demonstrate to Congress that the ability to dispose of worthless patents that only serve as rent seeking tools is detrimental to small businesses and new market entrants.

The technology sector in particular can be a vibrant field for small businesses because of low upfront costs opens the door to competitive entry. It is also a sector that traditionally enjoyed a broader range of investors willing to give new small firms a fighting shot. However, should Congress change Section 101 in order to expand what can receive a patent beyond ideas that are truly inventive, it will drive out small businesses in the technology space in favor of large incumbent corporations. Simultaneously, it will raise costs on the remaining large incumbents without any real advancement in society's collective knowledge, which, according to the Constitution, is the patent system's purpose.

b. What impact will broadening the subject matter that can be patented have on consumers?

1. Patent Troll Lawsuits Kill Jobs and Raise Prices

Since its creation in 1982, the Federal Circuit has approved patents on basic ideas, implemented with generic computers, that it should have rejected based on Supreme Court precedents such as *Parker v. Flook* and *Gottschalk v. Benson*. That problem got even worse after the Federal Circuit's decision in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, in 1998, which chipped away any remaining restrictions on software patents, and allowed patents on "business methods."

By the 2000s, this lenient application of Section 101 produced vast numbers of broadly-drawn software patents that sustained an epidemic of abuses by "patent trolls," or "non-practicing entities" (NPEs)—companies that produce no services or products, but simply assert patents to leverage litigation costs and extract cash settlements from operating companies.

Patent troll litigation has caused staggering economic losses to the U.S. economy. A 2011 study found that patent troll lawsuits cost publicly traded firms an average of $83 billion per year from 2007 to 2010. That's more than one-quarter of US industrial research and development over the same time period. By 2011, patent trolls cost publicly traded firms $500 billion since 1990. Only a tiny fraction of that amount—less than 10 percent, even before legal costs—was actually returned to original inventors.[1] A separate study showed that the direct legal costs of NPE litigation alone cost firms $29 billion in 2011.[2]

[1] Bessen, James E. and Meurer, Michael J. and Ford, Jennifer Laurissa, *The Private and Social Costs of Patent Trolls*, Boston Univ. School of Law, Law and Economics Research Paper No. 11-45 (September 19, 2011), available at: https://ssrn.com/abstract=1930272.
[2] Bessen, James E. and Meurer, Michael J., *The Direct Costs from NPE Disputes*, 99 Cornell L. Rev. 387 (2014), available at: https://ssrn.com/abstract=2091210.

These NPE litigations kill jobs, raise prices across the entire economy, and directly lessen research and development budgets. Losing a lawsuit against an NPE, either through a court decision or a settlement, reduces a firm's research and development by 20%, on average, compared to identical firms that were not targeted by NPEs.[3]

Only in recent years did the Supreme Court give strength and meaning to Section 101, by deciding *Alice v. CLS Bank*. District courts were finally empowered to eliminate patents that impose the greatest costs, while contributing nothing. The interests of consumers and innovators would be served by further strengthening Section 101's "gatekeeping" function, which ensures patents only go to actual inventions.

Overly Broad Patenting Hurts Research and Job Creation

Allowing patents on more subject matter will raise prices across the economy. Giving patent owners the power to raise prices, by way of licensing or excluding competitors, is the very purpose of a patent.

In an ideal situation, the limited monopoly provided by a patent can be used to spur innovation—for instance, by allowing a firm to recoup research and development costs. This boost to innovation is the sole justification for the increased burden that patents put on consumers. Unfortunately, U.S. courts strayed far from that ideal. For at least two decades, courts have allowed far too much patenting in many areas of technology, granting unwarranted monopolies across all sectors of the economy.

Expanding patentable subject matter at this time will not encourage innovation. What is needed are more clear guidelines like the Supreme Court's *Alice v. CLS Bank* decision, which finally placed limits on the most harmful software patents—those that use generic computer language but don't actually require any specific hardware or software. Before Alice, many software patents didn't describe anything that humans with pens and paper could not.

Empirical research now shows how out of balance our patent system has been. Today, *more* limitations on patents, not fewer, will encourage R&D and create new jobs—while allowing consumers to benefit from real competition. That will also allow the patent system to serve the purpose the Constitution's authors intended: promoting technological progress and economic growth.

Following *Alice*, firms that were acquiring business methods decreased their patenting activity and increased their R&D intensity by 9.34%, relative to the mean R&D spending in their

[3] Cohen, Lauren and Gurun, Umit and Kominers, Scott Duke, *Patent Trolls: Evidence from Targeted Firms*, Harvard Business School Finance Working Paper No. 15-002 (June 8, 2018), available at: https://ssrn.com/abstract=2464303.

industry. [4] The *Alice* decision led firms away from a "litigation channel" in which they were constantly filing for defensive patents, and towards increasing R&D.

c. Could the proposed reforms increase consumer prices? If so, in what industries or on what products?

Changing Section 101 Will Increase Prices for Software-Based Medical Diagnostics and Health Care Services

A specific goal of the draft bill would be to allow additional patenting of medical diagnostic tests. Allowing such patents will cause long-term harm to consumers, even after the patents expire.

For example, Myriad Genetics was allowed to maintain a monopoly on critical tests around the BRCA1 and BRCA2 genes, which relate to some types of breast and ovarian cancer. Myriad's illegitimate patents were challenged by public-interest groups and finally eliminated in 2013, when the Supreme Court decided the *AMP v. Myriad Genetics* case. Lower-priced competitors immediately came onto the market.[5]

The patents that the Supreme Court rejected did not claim a new technology for testing for the presence of certain mutations in human genes (and thus the likelihood the human carrying them would develop cancer); it just claimed the idea of doing so by relying on the technological advances and discoveries made by others. Allowing companies to patent the idea of using information in the human body without claiming any particular (let alone inventive) way of using that information directly threatens access to tools for basic research. The information that our genes carry is not a human invention. Neither is the idea of using that information without anything else that could be the applicant's own work.

Removing Section 101's prohibitions on patenting laws of nature, things that occur in nature, and abstract ideas will particularly affect the fields of medical diagnostics and health monitoring, which are increasingly software-based. Congress should be skeptical of allowing patent thickets that thwart innovation, impose barriers to entry, and drive up costs in these emerging markets. As the platforms for performing medical tests and gathering patient information become ubiquitous and widely available (at least partly because patents underlying those advances have expired), the public should have access to the benefits that come from employing those advances.

[4] Srinivasan, Sridhar, *Do Weaker Patents Induce Greater Research Investments?* (December 22, 2018), available at: https://ssrn.com/abstract=3185148.

[5] PR Newswire, *DNATraits to Offer Low Cost BRCA Breast and Ovarian Cancer Gene Testing in US* (June 13, 2013), https://www.prnewswire.com/news-releases/supreme-court-ruling-today-allows-dnatraits-to-offer-low-cost-brca-breast-and-ovarian-cancer-gene-testing-in-us-211426171.html.

EFF knows firsthand that Section 101 helps remove barriers to entry in the field of health monitoring products and services. One of our clients in recent years, Justus Decher, invented a new system for remote monitoring of patients. Decher's system was particularly popular with rural hospitals, where it was a great burden for elderly patients to travel long distances for simple health monitoring tasks.

Decher's Omaha-based business was almost snuffed out before it got off the ground. He was threatened by a non-practicing entity called MyHealth, which held a patent that generically claimed "remote patient monitoring." MyHealth demanded $25,000 as a patent license payment, and sued several of Decher's competitors.
When MyHealth's patent was analyzed by a court, it was found to be ineligible under Section 101. If the draft bill presently under consideration had been the law of the land, MyHealth's patent would have survived through advanced stages of litigation. The non-practicing entity could have extracted millions from the health-monitoring industry, and shut down the companies that didn't have enough resources to withstand years of litigation. It's just one example of why a robust Section 101 is critical to keeping prices low in the health care field.[6]

The Proposed Changes Will Inhibit Research and Development of Free and Open Source Technologies

The patent system assumes that innovation requires large investments that can only be recovered reliably if exclusive rights—and the ability to charge supra-competitive prices—can be assured. But many innovators and businesses do not need or want to use that model. They want to maximize access to the fruits of their inventive efforts by ensuring access at the lowest possible cost to users, and sometimes at no cost at all.

We see examples of these kinds of development efforts every day at EFF. So do millions of people in this country and around the world who use free and open source software (software whose source code is made available for free for others to use and modify), like Mozilla's Firefox browser.[7] Even big technology companies like Google and Microsoft develop and rely on open source software in their products. The importance of having Firefox as an alternative in the browser market cannot be understated; it has helped create and sustain competition, and contributed to better corporate ethics among technology companies through its approach to user privacy, and respecting users' choices.

More and more, we are seeing the model that free and open source software projects set being adopted by cutting-edge innovation in emerging fields. One example is the Open Insulin Project.[8] Because of the staggering costs of insulin, which those with diabetes depend on, researchers are working on developing a protocol for making a low-cost version of insulin using

[6] *See* https://www.eff.org/alice/alice-saves-medical-startup-death-telehealth-patent.
[7] Shankland, Stephen, *Mozilla's radical open-source move helped rewrite rules of tech*, (Mar. 29, 2018), https://www.cnet.com/news/mozilla-open-source-firefox-move-helped-rewrite-tech-rules-anniversary/.
[8] Black, Erin, *Insulin has become so expensive that this diabetic is trying to make his own*, (Jan. 26, 2019), https://www.cnbc.com/2019/01/25/open-insulin-is-making-insulin-in-a-lab-to-prove-it-can-be-cheaper.html.

existing technology platforms that others around the country and world would have be able to access affordably and reliably.

The Open Insulin Project is working on this crucial goal having raised initial funding in the amount of $16,656.[9] They are not relying on massive investment costs that will need to be recouped with certainty decades later. They are relying today on the commitment, enthusiasm, and ingenuity of their contributors, and hoping to develop knowledge that will be accessible to all at affordable prices that they may not even be the ones to earn. This type of model, well-established in the software field, is becoming more and more viable in biotechnology.

But allowing patents on abstract ideas, laws of nature, and naturally-occurring matter will create risks that open source projects cannot take on: the risk of an injunction that would prevent them from working or sharing the fruits of their labor with others. While injunctions are relatively rare in the software field since the Supreme Court's decision in *eBay v. MercExchange*, they remain relatively prevalent in the pharmaceutical and biotechnology industries because of the importance of first entry into these markets. Thus, the proposed changes to Section 101 will threaten to raise consumer prices and prevent altogether the development of affordable and accessible technologies.

[9] *See* http://openinsulin.org/about-the-project/.

Answers of Alex H. Moss to Written Questions from Senator Makie K. Hirono
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1. Last year, Judge Alan Lourie and Judge Pauline Newman of the Federal Circuit issued a concurring opinion to the court's denial of *en banc* rehearing in *Berkheimer v. HP Inc.*, in which they stated that "the law needs clarification by higher authority, perhaps by Congress, to work its way out of what so many in the innovation field consider are § 101 problems."

   Do you agree with Judges Lourie and Newman? Does § 101 require a Congressional fix or should we let the courts continue to work things out?

EFF disagrees with Judges Lourie and Newman that Congress needs to roll back the Supreme Court's decisions in *Myriad*, *Mayo*, and *Alice*—not to mention the cases on which those precedents rely, such as *LeRoy v. Tatham*, *O'Reilly v. Morse*, *Gottschalk v. Benson*, and *Parker v. Flook*. Research confirms that Section 101 is working and, in fact, becoming more and more consistent in its application in district courts as well as the Federal Circuit. We urge Congress to rely on data, not dicta of unelected judges.

The data shows that there is no lack of clarity. The Federal Circuit agrees with district courts about the application of Section 101 the overwhelming majority of the time—in fact, more often than it does on other patent issues. A study found that for the three years following the Alice decision, the Federal Circuit had an affirmance rate of about 88% in § 101 cases.[1] That contrasts with an overall affirmance rate in patent cases of around 75%.[2]

Even those numbers understate the Federal Circuit's affirmance rate on Section 101 because "[t]hey omit non-precedential opinions and summary affirmances under Rule 36." *Id.* A separate study by Professors Paul Gugliuzza and Mark Lemley revealed that in over one hundred Rule 36 decisions over the same three-year time period following *Alice*, the Federal Circuit affirmed ineligibility decisions *more than 90%* of the time.[3] Research also shows an overall trend of increasing predictability on Section 101 issues following *Alice*. For example, data shows an affirmance rate of 57% for precedential cases from 2015 and 2016 along with a dramatic increase to an affirmance rate of 69% for 2016 and 2017."[4]

[1] Anapol, Jeremy and Schwaab, Andrew B., *How Unpredictable is the Alice Analysis?*, (Oct. 16, 2018), https://www.knobbe.com/news/2018/10/how-unpredictable-alice-analysis#_ednref10.
[2] *Id.*
[3] Gugliuzza, Paul R. and Lemley, Mark A., *Can a Court Change the Law by Saying Nothing?*, 71 Vanderbilt L. Rev. 764, 765 (2018), available at: https://ssrn.com/abstract=3015459.
[4] Anapol and Schwaab, *supra* note 1.

The increasingly high affirmance rates seen since *Alice* are consistent with the view Judge Dyk of the Federal Circuit has expressed—"that the *Mayo/Alice* framework works well with respect to abstract ideas."[5]

Judges Lourie and Newman are not calling for congressional action because they find the law too confusing to apply; they simply disagree with the Supreme Court about the value of patents, particularly on laws of nature and things that occur in nature. Judge Lourie wrote the *Myriad* decision, allowing patents on naturally-occurring DNA in the human body, and *Mayo*, allowing a patent on a method of dosing based on the body's natural metabolism, that the Supreme Court reversed under Section 101.

Judge Lourie's and Judge Newman's views cannot be squared with prohibitions on gene patents. Importantly, after calling for a congressional fix in his *Berkheimer* concurrence, Judge Lourie opined that, contrary to the Supreme Court's decision in *Myriad*, "finding, isolating, and purifying such products are genuine acts of inventiveness, which *should* be incentivized and rewarded by patents."[6] Judge Lourie's call to action is thus a call to undo *Myriad* by making the mere discovery of natural products—such as human genes and their phenotypic associations—eligible for patent protection. There is no change Congress could make that would satisfy Judge Lourie's criticisms of Section 101 without sacrificing the rule against patents on human genes and the information they carry.

To the extent Congress believes some change is necessary to protect particular kinds of advances in the field of medical diagnostics, it should consider far more targeted and less drastic approaches than a wholesale re-write of Section 101. EFF urges the Senate to consider non-patent approaches as well as the extent to which non-patent protections that already exist (such as data exclusivity for biologic products and copyright protection for semiconductor chips) leave any gaps in the availability of exclusive rights at all.

2. The Federal Circuit rejected a "technological arts test" in its *en banc Bilski* opinion. It explained that "the terms 'technological arts' and 'technology' are both ambiguous and ever-changing." The draft legislation includes the requirement that an invention be in a "field of technology."

   a. Do you consider this a clear, understood term? If so, what does it mean for an invention to be in a "field of technology"?

"Field of technology" is not a clear term with a well-understood meaning. Dictionaries, which courts will look to when interpreting new statutory language, establish the breadth of meanings that the term could carry. For example, Merriam-Webster defines "technology" as: "the practical application of knowledge especially in a particular area," "a capability given by the practical application knowledge," "a manner of accomplishing a task especially using technical processes,

[5] *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1288 (Fed. Cir. 2015) (Dyk, J., concurring in denial of en banc rehearing).
[6] *Berkheimer v. HP Inc.,* 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Lourie, J., concurring in denial of en banc rehearing).

methods or knowledge," and "the specialized aspects of a particular field of endeavor."[7] Practically anything an applicant could claim would likely fall within a field of technology if definitions such as those are applied. It is hard to imagine anything in the real world that would not in some respect qualify as a "practical application of knowledge" or "a capability given by the practical application of knowledge."

Practically speaking, it means next to nothing for a claimed invention to be in a "field of technology." Cases like *Bilski v. Kappos*, 561 U.S. 593 (2010) demonstrate how patent lawyers will argue that ineligible ideas qualify as technological inventions. *See id.* at 612 (rejecting argument that applying the idea of hedging risk to commodities and energy markets made claims eligible for patent protections).

Moreover, the way the word "useful" is defined in this proposal would make Section 101 incomprehensible if actually applied to the proposed new version of that section. According to the new Section 100(b): "The term 'useful' means any invention or discovery that provides specific and practical utility in any field of technology through human intervention."

b. The European Union, China, and many other countries include some sort of "technology" requirement in their patent eligibility statutes. What can we learn from their experiences?

In Europe, there is an explicit rule against patenting "mathematical methods" and "programs for computers." However, that prohibition is limited by guidelines allowing patents on computer programs that have a "technical character." As applied in practice, the European Union's rules for patenting software produce results that are roughly the same as ours under the current version of Section 101.[8] But that's because the guidelines requiring "technical" aspects come with prohibitions on patenting software alone. What we can learn from Europe is that adding a "technical" or "technological" requirement is not enough, by itself, to prevent patents that the European and U.S. Patent Offices would both reject today.

The lessons to learn from the substantive requirements of China's patent law are far from clear. China is granting lots of patents, but the vast majority of them are extremely low-value.[9] The vast majority of them are not even patents for "inventions."[10] And applicants' motivations derive at least partly from government intervention; the Chinese government provides financial and

[7] Merriam-Webster Dictionary, Definition of "Technology," available at: https://www.merriam-webster.com/dictionary/technology (last visited June 26, 2019).
[8] European Patent Office, Guidelines for Examination, Part G., Section 3.6, available at: https://www.epo.org/law-practice/legal-texts/html/guidelines2018/e/g_ii_3.htm (last visited June 26, 2019).
[9] Bloomberg News, *China Claims More Patents Than Any Country—Most Are Worthless*, (Sept. 26, 2018), available at: https://www.bloomberg.com/news/articles/2018-09-26/china-claims-more-patents-than-any-country-most-are-worthless.
[10] *Id.* (Invention patents only represented 23% of patents granted in China in 2017.).

other initiatives for new patent applications (but not renewals, leading to rates of patent abandonment as high as 91% for design patents).[11]

There are also international indicators of the low quality of patents currently being granted. In 2016, 96% of applications from Chinese entities were filed domestically only, with only 4% filed in foreign patent offices, e.g., in U.S., Europe, and Japan.[12] That means virtually none of the applications originating in China are "triadic patents" (patents filed jointly in the patent offices of Japan, the United States, and European Union), which are widely considered "the gold standard" for patent protection.[13] The standards China is applying in patent examination do not provide lessons we should follow.

But more importantly, we have no reason to fear when patents are granted in foreign countries, but not the U.S. Patents granted only abroad cannot stop anyone in the U.S. from making, using, or selling anything on U.S. soil. In fact, a glut of foreign patents could give U.S.-based developers and start-ups a competitive edge *over* their foreign rivals. Granting more software patents leads to software and e-commerce companies facing more patent licensing demands, often based on the threat of lawsuits. Those that can afford to fight back in court will do so by spending less on engineers and more on lawyers. Congress should not rewrite U.S. patent law because of unsubstantiated concerns about the practices of foreign patent offices.

c. Is a claim that describes a method for hedging against the financial risk of price fluctuations—like the one at issue in the *Bilski* case—in a "field of technology"? What if the claim requires performing the method on a computer?

Plenty of patent lawyers would argue that claims like the one at issue in *Bilski* are within a "field of technology" simply because they relate to technological fields. For example, in *Bilski*, the patent claimed a method of hedging risk for the commodities and energy industries. The patent applicant argued that applying that method to such technological industries was enough to qualify as eligible for patent protection under cases like *Diamond v. Diehr*, 450 U.S. 175, 182 (1981). *See Bilski*, 561 U.S. at 610-12. The Supreme Court rejected that argument by relying on precedents that would be abrogated if the proposed changes to the Patent Act become law. There will no longer be a way to reject arguments that simply applying an abstract idea to a brick-and-mortar industry is enough to make it technological, and therefore eligible for patent protection.

Patent applicants will attempt to make the same kinds of arguments by arguing that the use of a generic computer renders a patent claim "technological." Indeed, before and after *Alice*, patent applicants and owners have argued for patent-eligibility based on claim limitations requiring a generic computer. For example, in *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat. Ass'n*, 776 F.3d 1343, 1348 (Fed. Cir. 2014), the patent owner argued that claims requiring the use of a scanner to create digital images of paper documents tied the claims to "a particular technological environment," and thus rendered them patent-eligible, but the Federal

[11] *Id.* ("Since 2008, as part of China's national policy to encourage innovation, companies certified as "high-tech firms" have won significant tax cuts and annual subsidies of 500,000 yuan in provinces like Hainan.").
[12] Center for Strategic and International Studies, China Power Team. *Are patents indicative of Chinese innovation?*, (February 15, 2016), available at: https://chinapower.csis.org/patents/.
[13] *Id.*

Circuit rejected that argument based on precedents applying *Alice*. *Id.* (citing *Ultramercial, Inc. v. Hulu, LLC,* 772 F.3d 709, 715–16 (Fed.Cir.2014); *buySAFE,* 765 F.3d at 1355). Allowing patents on anything "in a field of technology" will open the door to ineligible patents like the one

in *Content Extraction* based on entirely generic and conventional equipment, including things like document scanners, generic computers, and smartphones.

Applicants should not be able to use advances made by others that have become ubiquitous to monopolize abstract ideas and other basic tools of research.

d. What changes to the draft, if any, do you recommend to make the "field of technology" requirement more clear?

EFF does not support any of the currently proposed changes to Section 101. But if Congress truly wishes to achieve clarity, it could simply remove the word "process" from Section 101. That will ensure patents only issue on new and useful machines, manufactures, compositions of matter, and new and useful improvements thereof. And it will resolve conclusively any questions about the ineligibility of patents on methods of organizing human activity, purely mental processes, and performing mathematical equations.

3. Sen. Tillis and Sen. Coons have made clear that genes as they exist in the human body would not be patent eligible under their proposal.

   Are there other things that Congress should make clear are not patent eligible? There are already statutes that prevent patents on tax strategies and human organisms. Are there other categories that should be excluded?

We agree with Justices Sotomayor, Ginsburg, and Breyer that business methods and methods of organizing human activity should be categorically ineligible for patent protection. *See Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 227 ("I adhere to the view that any "claim that merely describes a method of doing business does not qualify as a 'process' under § 101." (citing *Bilski v. Kappos,* 561 U.S. 593, 614 (2010) (Stevens, J., concurring in judgment); *In re Bilski,* 545 F.3d 943, 972 (Fed Cir. 2008) (Dyk, J., concurring) ("There is no suggestion in any of th[e] early [English] consideration of process patents that processes for organizing human activity were or ever had been patentable")) (Sotomayor, J., concurring).

4. I have heard complaints that courts do not consistently enforce Section 112 with respect to claims for inventions in the high tech space.

   a. Are these valid complaints?

Yes. Section 112 in practice does little to prevent broad and ambiguous patent claims in software-related fields. By contrast, there is a well-established body of law that strictly applies the written description and enablement requirements to biotechnological inventions. *See, e.g.*, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

Unfortunately, these requirements are not applied with equal rigor or consistency in cases involving software patents.

That is largely because software patents often require so little technological complexity and expertise that it is relatively easy for patent owners to argue that a person of ordinary skill in the field would be able to accomplish the invention without needing any more information from the

patent specification. Until the doctrines of written description and enablement are applied more consistently and strictly to software patents, any changes to Section 112 will have little to no effect in preventing the Patent Office from granting broad and ambiguous software patent claims.

b. Do the proposed changes to Section 112 adequately address those complaints and limit the scope of claims to what was actually invented?

No. The proposed changes to Section 112 threaten to create new questions and more uncertainty. For example, what does it mean for an element of a claim to be "expressed as a specified function without the recital of structure, material, or acts in support thereof"? Neither the term "specified function" nor "acts in support thereof" are found in anywhere in the current statute or existing case law. Even worse, the proposed change requiring disclosures that "support" a "specified function" appears broader on its face than the current requirement of "corresponding structure" that, according to case law, must also be "clearly linked" to the claim element at issue.

c. Are you concerned that the proposed changes will make it too easy for competitors to design around patent claims that use functional language?

No. Patent owners would still be able to prevent competitors from using against anything that is "equivalent" to the supporting structure, material, or acts disclosed in the specification under the doctrine of equivalents. That doctrine provides that something which performs substantially the same result in substantially the same way as a claimed invention infringes. Because patent owners can still sue substantially similar implementations, competitors will still not be able to avoid infringement liability with insubstantial design changes.

5. There is an intense debate going on right now about what to do about the high cost of prescription drugs. One concern is that pharmaceutical companies are gaming the patent system by extending their patent terms through additional patents on minor changes to their drugs. My understanding is that the doctrine of obviousness-type double patenting is designed to prevent this very thing.

   The Federal Circuit has explained that obviousness-type double patenting "is grounded in the text of the Patent Act" and specifically cited Section 101 for support.

   Would the proposed changes to Section 101 and the additional provision abrogating cases establishing judicial exceptions to Section 101 do away with the doctrine of obviousness-type double patenting? If so, should the doctrine of obvious-type double patenting be codified?

Yes, the proposed changes would do away with the doctrine of obvious-type double patenting. As the Federal Circuit recently stated, "§ 101 forbids an individual from obtaining more than one patent on the same invention, *i.e.,* double patenting." *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1372 (Fed. Cir. 2014). No other section of the Patent Act could support an obvious-type double patenting rejection. Neither the claims nor the disclosures in an applicant's previously-filed patent application can qualify as prior art against the same applicant's later-filed application under § 102 or § 103. Only the doctrine of obvious-type double patenting, which derives from Section 101 of the Patent Law, supports a rejection of this type.

The best way to preserve this doctrine is to preserve Section 101 in full. That will preserve the obvious-type double patenting doctrine as well as other grounds of invalidity under Section 101, but outside the *Mayo*/*Alice* framework.

Even if codifying the obviousness-type double patenting doctrine were possible, that would not protect important limitations on patent-eligible subject matter derived from Section 101 as written today.

One example is the rule against patent-eligibility on the basis of printed matter—*i.e.*, the content or substance of information with no functional relationship to the claimed invention. As the Federal Circuit has held, "[c]laim limitations directed to the content of information and lacking a requisite functional relationship are not entitled to patentable weight because such information is not patent eligible subject matter under 35 U.S.C. § 101." *Praxair Distribution, Inc. v. Mallinckrodt Hosp. Prod. IP Ltd.*, 890 F.3d 1024, 1032–33 (Fed. Cir. 2018) (citations omitted).

The doctrine is relevant to patents in a wide range of technologies. For example, the Federal Circuit's current case law establishes "that merely adding an instruction sheet or other informational content to a drug product is not sufficient to create a functional relationship, even if required by the FDA for approval." *Id.* (citation omitted). The court has similarly held that, where "there [i]s no functional relationship between claimed instructions and a diagnostic kit," the instructions cannot confer patent-eligibility. *Id.* (citation omitted). Removing Section 101's protections will thus remove the protections against patents on information that has no function.

Another is the rule against patenting copies of ineligible subject matter. For example, in *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333, 1337 (Fed. Cir. 2014), the Federal Circuit held claims on a cloned sheep ineligible for patent under Section 101. The court explained that as in *Myriad*, the patent owner, Roslin had "did not create or alter any of the genetic information of its claimed clones, [n]or did [Roslin] create or alter the genetic structure of [the] DNA used to make its clones. . . . Instead, Roslin's chief innovation was the preservation of the donor DNA such that the clone is an exact copy of the mammal from which the somatic cell was taken. Such a copy is not eligible for patent protection." *Id.* Because "Roslin's claimed clones are exact genetic copies of patent ineligible subject matter," they were "not eligible for patent protection." *Id.*

Because Section 101 already codifies all of these important limitations on patent-eligible subject matter, preserving it as written is the best way to ensure they continue to exist.

6. In its *Oil States* decision, the Supreme Court explicitly avoided answering the question of whether a patent is property for purposes of the Due Process Clause or the Takings Clause.

   What are the Due Process and Takings implications of changing Section 101 and applying it retroactively to already-issued patents?

Because the changes proposed would make Section 101 effectively useless as a means of invalidating issued patents, it's unlikely to have any effect on already-issued patents. It is virtually impossible to imagine a patent that would survive today's Section 101, but not the proposed new version. We therefore do not foresee retroactivity questions arising in practice.

However, we are concerned about the attempts to apply a new version of the statute to previously-*denied* applications and *invalidated* patents in pending litigation. To avoid the flood of unnecessary litigation retroactivity would create, Congress should make the new section 101 available only to applications filed on or after its effective date. Although claims based on prior invalidity decisions would not raise judiciable due process or takings claims, they would take material out of the public domain, shrinking public access to basic research tools and products.