

## Answers to Questions for Phil Johnson From Chairman Tillis

### 1. You represent a coalition of some of the biggest companies in the intellectual property arena.

#### [A] From the perspective of your association, how has the current state of patent eligibility hindered their ability to bring new and innovative products to market?

*Answer:* Yes. As many of the witnesses have confirmed, the current state of patent eligibility law has injected enormous uncertainty and unpredictability into whether inventions in many important fields will ultimately be held to be patent eligible. While there is a degree of risk in all R&D, that risk is much greater when the research is transformational rather than incremental. Because transformational research is more basic, under the current law it is much more likely to be found patent ineligible as being “abstract,” directed to a “law of nature,” or claiming a “natural phenomenon.”

As many of the witnesses involved in early stage research have explained, the availability of reliable patent protection is essential to the invention and development of fundamental breakthroughs. Patents are needed to justify the formation of startups, to attract venture capital and/or to license development partners to do the work needed to commercialize the invention. As we have also heard, if patent protection is not reliably available further R&D won't happen and nothing will be commercialized, to the detriment of those who could have benefited from it.

In some fields, it may be possible to keep the invention as a trade secret, yet still commercialize it. Examples are the formula for Coca Cola, Google's search algorithms, targeted personal advertising methods, and certain proprietary manufacturing methods. In other fields, trade secrets are not a realistic option because the invention is disclosed by its commercialization, because the risk of inadvertent disclosure or misappropriation is too high, or because the rules or regulations applying to the research activity and/or its commercialization demand public disclosure.

In certain situations, the nature of the business may make the availability of patent protection more or less important. For example, dependable patents are more likely to be of critical importance to small competitors or new entrants in an industry,<sup>1</sup> whereas they may be less important to well entrenched and/or dominant competitors who benefit from other advantages, including, for example, established customer goodwill, supply chains and other economies of

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<sup>1</sup> See Morinville Testimony at page 2.

scale.

In the software and entertainment fields, copyright protection often provides protection against copying, which perhaps explains the unprecedented influx of capital into the development of copyrightable content. While some forms of available clinical trial data protection may help to encourage the development of therapeutic biologics, these forms of protection are time limited and not available against competitors who conduct their own clinical trials and apply for BLA approvals for biologics that compete in treating the same or similar indications.

Current patent eligibility law also discourages research into products or methods that are likely to gain patent coverage through the issuance of only one, or just a few patents, as opposed to a great many patents. A breakthrough new drug is an example of an important invention that is often covered by no more than a handful of patents, whereas today's mobile phones may be covered by hundreds of patents. In the event of product copying, the odds strongly favor the owner of hundreds of relevant patents over the one who has just a few, particularly in our current system in which there is a lower probability of success in defending the validity of any given patent.

For these reasons, the current state of patent eligibility law (a) discourages inventors and their investors from pursuing transformational breakthroughs in favor of incremental product improvements; (b) discourages research that depends on patent protection as opposed to trade secrets; (c) discourages research and development by inventors who are required to publicly disclose their research; (d) discourages research and development by independent inventors, small businesses and new entrants; (e) discourages investment in activities in need of patent protection as opposed to investment in activities that are protectable by copyrights or other forms of competitive protection; and (f) discourages research and development into products that are likely to be protected by relatively few (basic) patents as opposed to many (incremental) patents.

**[B] What areas of research, development and innovation are they no longer investing in or pursuing because of the current jurisprudence?**

Investors, startups and established companies are no longer investing in research and development of inventions where the perceived degree of unreliability of patent protection causes the projected return on the investment ("ROI") to drop below the levels that are required to justify the cumulative risk of the proposed undertaking. Current eligibility law is an important factor, but not the only factor, affecting the dependability of patent protection. Examples of other factors are the pro-challenger nature of USPTO IPR proceedings, the relative unavailability of preliminary and final injunctions to stop infringement, and the availability of a number of other judge-made defenses that have evolved to make it difficult to successfully enforce valid patents.

As many of the witnesses appearing before this Subcommittee have confirmed, inventive efforts relating to the life sciences and software industries,<sup>2</sup> including those denying patent eligibility for

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<sup>2</sup> Fiacco Testimony at pages 8-9; Partridge Testimony at page 4; Hadad Testimony at pages 8-9; Morinville at 12-13; Brandon Testimony at pages 1-2; Schechter Testimony at pages 7; Chotkowski Testimony at 5; O'Neil Testimony

isolated natural products,<sup>3</sup> diagnostics,<sup>4</sup> pharmaceuticals,<sup>5</sup> methods of treatment,<sup>6</sup> vaccines & antibiotics,<sup>7</sup> personalized medicine,<sup>8</sup> biotechnology products,<sup>9</sup> genetic innovations,<sup>10</sup> medical devices,<sup>11</sup> computer implemented inventions,<sup>12</sup> quantum computing,<sup>13</sup> data compression algorithms,<sup>14</sup> 5G,<sup>15</sup> blockchain,<sup>16</sup> the internet of things,<sup>17</sup> polar coding,<sup>18</sup> electronic games,<sup>19</sup> artificial intelligence<sup>20</sup> and many others are negatively affected and/or not being undertaken because of the effects of current patent eligibility law.

## **2. [A] Can you talk about the national security implications of our failure to correct this area of the law?**

*Answer:* As former USPTO Director David Kappos explained, artificial intelligence, quantum computing and 5G are all fields bearing directly on our national security yet are being disproportionately denied patent protection as a result of current patent eligibility law.<sup>21</sup>

As Mr. Birchak explained in his written testimony (at page 8):

Foreign dominance of any critical technology presents significant national security concerns, as competitors, many with ties to hostile governments, control wireless networks, computer hardware, medical devices, and other technologies used by individuals, businesses, and governments in the United States. The World Intellectual Property Organization (WIPO) recently reported that China is now rivaling the U.S. in the patenting of Artificial Intelligence technologies, potentially providing China with a competitive advantage in the further development and control of AI technology.<sup>22</sup>

As explained by Laurie Self, of Qualcomm,

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at page 3.

<sup>3</sup> Knowles testimony at 28; Sauer testimony at pages 4-6; Hill Testimony at 10-12.

<sup>4</sup> Knowles testimony at 28; Brandon Testimony at page 2.

<sup>5</sup> Taylor testimony at pg. 6; Salsberg Testimony at page 4.

<sup>6</sup> Salsberg Testimony at page 4

<sup>7</sup> Sauer testimony at page 6; Derzko at page 11.

<sup>8</sup> Hadad Testimony at pages 7-8; Derzko Testimony at 3-4, 7-9; Hill Testimony at 9-10; Spetzler Testimony at pages 3-6.

<sup>9</sup> Taylor testimony at pg. 6; Sauer Testimony at pages 1-3.

<sup>10</sup> Merino Testimony at page 2.

<sup>11</sup> Taylor testimony at pg. 6; Birchak Testimony at pages 7-8; Salsberg Testimony at page 4.

<sup>12</sup> Schechter Testimony at pages 2-4.

<sup>13</sup> Kappos testimony at pages 2-3; Schechter Testimony at pages 3-4.

<sup>14</sup> Dupont Testimony at pages 1-4.

<sup>15</sup> Kappos testimony at pages 2-3; Self Testimony at pages 2-5; Chotkowski Testimony at 5.

<sup>16</sup> Schechter Testimony at pages 5.

<sup>17</sup> Schechter Testimony at pages 5.

<sup>18</sup> Self Testimony at pages 6.

<sup>19</sup> Blankstein Testimony at pages 1-3.

<sup>20</sup> Kappos testimony at pages 2-3; Schechter Testimony at pages 3-4; Hill Testimony at pages 13-15.

<sup>21</sup> Kappos testimony at pp. 2-3.

<sup>22</sup> See World Intellectual Property Org., *Technology Trends 2019: Artificial Intelligence* (2019), at 15–16, <https://www.wipo.int/edocs/pubdocs/en/wipopub1055.pdf>.

The importance of maintaining U.S. leadership in global technology innovation cannot be overstated. Foreign dominance of any critical technology presents significant national security concerns, as competitors, many with ties to hostile governments, control wireless networks, computer hardware, medical devices, and other technologies used by individuals, businesses, and governments in the United States.

5G in particular carries an elevated risk of foreign control because U.S. companies are not competitive in all areas of the 5G ecosystem. Today's mobile 5G ecosystem is built upon a foundation of 5G R&D and standards setting that enables the entire wireless environment. The other elements—mobile phones and other devices, 5G infrastructure, and mobile semiconductors—each present their own challenges and opportunities for U.S. leadership in the broader 5G environment, and key implications for U.S. national security.<sup>23</sup>

These are valid concerns that deserve our attention, particularly in the current environment where cyber and ransomware attacks on governments and private enterprises are becoming more common, and where our national defense is increasingly dependent on digital superiority. The same can be said of the other areas of innovation that are currently being discouraged because in a broader sense our national security depends on technological superiority and encompasses other areas including, for example, biosecurity.

**[B] Do you get a sense from your member companies that innovation is going to be driven overseas unless we fix this mess?**

*Answer:* Research and development based companies, such as the members of 21C, favor designing and developing state-of-the-art products for sale in markets where the market success of those products will be protected by reliable patent protection. This helps to ensure that if their inventions are commercially successful, they will not be knocked off by copyists, and will likely receive a fair return on their investments. In jurisdictions where patent eligibility is uncertain, research and development are discouraged.

In many fields, the best way to ensure commercial success is to locate R&D locally within the target market, so that the products may be designed to meet local requirements and tailored to meet local needs and tastes. In then deciding where to manufacture the newly invented product, companies consider a great many factors, including the proximity of the point of manufacture to the R&D facility that originated the product, the proximity of the point of manufacture to the target market, the cost of manufacturing in the location, the expected tax burden on the product, projected sales volumes and the availability of patent protection in the jurisdiction of manufacture.

For the United States to remain globally competitive in R&D, and to continue enjoy the fruits of domestic R&D targeted to our needs and tastes, several aspects of our patent system need to be improved, one of which is that of patent eligibility. Without patent eligibility reform, we will remain at a competitive disadvantage to Europe, China, and many other countries that offer patent eligibility for inventions now unavailable in the United States.

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<sup>23</sup> Self Testimony at 7.

**[A] Regarding our draft proposal, do you believe it would restore the predictability and stability to the system that your member companies need to continue innovating?**

*Answer:* Yes, as explained more fully in my written testimony, it is an important first step towards restoring the predictability and stability of our patent system.

**[B] Are there any changes to our draft proposal you'd suggest we make?**

*Answer:* As suggested in my written testimony, the phrase “in any field of technology” is potentially ambiguous. 21C had previously suggested instead using the phrase “in the useful arts” to thereby employ the term used in Article I, Section 8, Clause 8 of the Constitution. The term “useful art” was also included in the first patent act, the Patent Act of 1791, which began:

when any person shall have invented any new and useful art, machine, or composition of matter, or any new and useful improvement on any art, machine, or composition of matter, and shall desire to have an exclusive property in the same, he [shall as further specified apply for a patent].

As then understood, useful arts were practical applications. The Constitution further distinguishes “useful arts” from “science,” which at the time was a term referring to the more theoretical works of authors, which would be protected by copyright. The Patent Act of 1791 nonetheless recognized that inventions may stem from branches of science, doing so in its passage requiring enabling disclosure:

...he [the inventor] shall then deposit a description of the said inventions in writing and of the manner of using or process for compounding the same in such full, clear, and exact terms, as to distinguish the same from other things before known and to enable any person *skilled in the art or science of which it is a branch*, or with which it is most nearly connected to make, compound and use the same...(italics added)

Accordingly, the substitution of “in the useful arts” for “in any field of technology” in the current proposal would be entirely consistent with its Constitutional and historical underpinnings, and would complement the proposal’s requirement that to qualify as patent eligible subject matter the claimed discovery or invention must have both a specific and practical utility.

In addition, 21C continues to suggest that if any changes to Section 112 are to be proposed in draft legislation, they be made the subjects of a further vetting process similar to the roundtable process which led to the current patent eligibility proposal.



**Answers to the Questions for the Record for Mr. Phil Johnson**  
**Senate Committee on the Judiciary**  
**Subcommittee on Intellectual Property**  
**Hearing on “The State of Patent Eligibility in America: Part II”**  
**June 5, 2019**

**QUESTIONS FROM SENATOR BLUMENTHAL**

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?**

*Answer:* The current proposal does not broaden patent eligible subject beyond the scope it had before the recent spate of Supreme Court cases which imposed new ambiguous to be applied to inventions deemed to be directed to “abstract ideas,” “laws of nature,” “products of nature,” and “natural phenomenon.” As witnesses across the political spectrum testified during the recent hearings, the law of patent eligibility is now a “mess,” and it is impossible in many areas for would-be inventors to determine in advance whether their inventions will be patent eligible or not.

Returning patent eligibility law to its original scope will improve the clarity and predictability of the patent system, but not necessarily result in previously unpatentable subject matter becoming patent eligible. The result of this change will be to lift the disincentives that are now chilling innovation in the life sciences and software industries,<sup>1</sup> including those denying patent eligibility for isolated natural products,<sup>2</sup> diagnostics,<sup>3</sup> pharmaceuticals,<sup>4</sup> vaccines & antibiotics,<sup>5</sup> personalized medicine,<sup>6</sup> biotechnology products,<sup>7</sup> medical devices,<sup>8</sup> computer implemented

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<sup>1</sup> Fiacco Testimony at pages 8-9; Partridge Testimony at page 4; Hadad Testimony at pages 8-9; Morinville at 12-13; Brandon Testimony at pages 1-2; Schechter Testimony at pages 7.

<sup>2</sup> Knowles testimony at 28; Sauer testimony at pages 4-6.

<sup>3</sup> Knowles testimony at 28; Brandon Testimony at page 2.

<sup>4</sup> Taylor testimony at pg. 6.

<sup>5</sup> Sauer testimony at page 6; Derzko at page 11.

<sup>6</sup> Hadad Testimony at pages 7-8; Derzko Testimony at 3-4, 7-9.

<sup>7</sup> Taylor testimony at pg. 6; Sauer Testimony at pages 1-3.

<sup>8</sup> Taylor testimony at pg. 6; Birchak Testimony at pages 7-8.

inventions,<sup>9</sup> quantum computing,<sup>10</sup> 5G,<sup>11</sup> blockchain,<sup>12</sup> the internet of things,<sup>13</sup> polar coding,<sup>14</sup> electronic gaming, artificial intelligence<sup>15</sup> and many others.

The effects on industry of the proposed Section 100 & 101 reforms will be to clarify what subject matter is and is not eligible for patenting. This clarity will encourage research and development in the above-mentioned fields, and reduce the attraction of conducting those activities in foreign jurisdictions that now routinely grant patents on subject matter deemed patent ineligible under the current Supreme Court tests.

Universities should find it easier to license their inventions to startups and other development partners, who in turn will be more likely to attract the venture capital needed to advance the licensed technology towards commercialization. Ultimately, the U.S. will pioneer more transformational technologies and maintain its historical position as the world's leader in technological advances.

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

*Answer:* Consumers will be the ultimate beneficiaries of this reform, as they will benefit from the additional innovation that these changes spawn. They will also benefit from the U.S. jobs that will be created in R&D and manufacturing, and in the other activities that will be needed to meet worldwide demand.

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

*Answer:* For an innovation to be accepted by the market it must deliver a comparable benefit at a lower cost, an increased benefit at an incremental cost that is less than the increased value conferred, or a combination of the two. Stated simply, consumers won't pay for a new product or service unless its value is better than the value of other alternatives available to them.

When an innovation is one that lowers the cost of previously available goods or services, the commercialization of the innovation will tend to drive down the cost of preexisting alternatives. When the innovation provides greater benefit at prices that are attractive relative to preexisting alternatives, competitors may be forced to lower their prices for a time while they are spurred into making further improvements to their own products to maintain or increase their market shares.

Accordingly, the relative cost of a product or service cannot be fairly assessed without also assessing its benefit to the consumer. Advanced synthetic motor oils, for example, may be priced at twice the price of conventional motor oil, but last four

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<sup>9</sup> Schecter Testimony at pages 2- .

<sup>10</sup> Kappos testimony at pages 2-3; Schecter Testimony at pages 3-4.

<sup>11</sup> Kappos testimony at pages 2-3; Self Testimony at pages 2-5.

<sup>12</sup> Schecter Testimony at pages 5.

<sup>13</sup> Schecter Testimony at pages 5.

<sup>14</sup> Self Testimony at pages 6.

<sup>15</sup> Kappos testimony at pages 2-3; Schecter Testimony at pages 3-4.

times longer. Despite an initial higher cost, the benefit they confer makes them cheaper to consumers. The same is true across all industries.

Recognizing these economic principles, the more important issue is whether the applicable policies affecting innovations encourage or discourage them. An innovation that never occurs can neither improve the benefit conferred to the consumer or force the lowering of prices for existing products. Jurisdictions whose policies fail to encourage and reward innovation tend to perpetuate stagnant industries that become vulnerable to disruption from foreign competition. The presently proposed reforms to patent eligibility are an important step towards ensuring that the U.S. does not become such a jurisdiction.

**Answers to the Questions for the Record for Phil Johnson  
From Senator Mazie K. Hirono**

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?**

*Answer:* Yes. For the reasons I set forth in my written testimony, Congress needs to act to fix our current § 101 problems. The Supreme Court has declined many opportunities to address these problems, and the lower courts are constrained by the current Supreme Court precedent.

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"?**

*Answer:* As noted in my written testimony, the phrase "field of technology" is ambiguous because the words "technology" and "technological" have been used within the patent field in different contexts and jurisdictions to mean different things.

- 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?**

*Answer:* The European Union and China are examples of jurisdictions where "technology" or "technological" have different meanings. The European patent system is quite different than ours in many important respects, and there is an established body of precedent in Europe as to how these words should be construed within the European system. China's system is also quite different, but it is still new and is evolving rapidly. Attempting to import precedent from either of these jurisdictions would only create more confusion and uncertainty.

- 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?**

*Answer:* A claim for hedging against the financial risk of price fluctuations is and would be unpatentable because it is neither novel nor nonobvious (thus not meeting the requirements of Sections 102 and 103). As to running such a hedging or any other program “on a computer,” the addition of such a limitation today would not itself make an otherwise unpatentable claim patentable because in today’s world the mere use of a computer is old and obvious as to virtually every application. Our interests today should not be in hypotheticals that focus on things that are old and otherwise unpatentable, but on the future of what might be in promising fields such as artificial intelligence, personalized medicine and a host of others that will be important to improving the human condition.

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

*Answer:* 21C has suggested that if a replacement phrase is needed, the phrase “in the useful arts” should be substituted because this language is that of the authorizing clause of the US Constitution, Article I, Section 8, Clause 8. The term “useful art” was also included in the first patent act, the Patent Act of 1791, which began:

. . . when any person shall have invented any new and useful art, machine, or composition of matter, or any new and useful improvement on any art, machine, or composition of matter, and shall desire to have an exclusive property in the same, he [shall as further specified apply for a patent].

As then understood, useful arts were practical applications. The Constitution further distinguishes “useful arts” from “science,” which at the time was a term referring to the more theoretical works of authors, which would be protected by copyright. The Patent Act of 1791 nonetheless recognized that inventions may stem from branches of science, doing so in its passage requiring enabling disclosure:

...he [the inventor] shall then deposit a description of the said inventions in writing and of the manner of using or process for compounding the same in such full, clear, and exact terms, as to distinguish the same from other things before known and to enable any person *skilled in the art or science of which it is a branch*, or with which it is most nearly connected to make, compound and use the same...(italics added)

Accordingly, the substitution of “in the useful arts” for “in any field of technology” in the current proposal would be entirely consistent with its Constitutional and historical underpinnings, and would complement the proposal’s requirement that to qualify as patent eligible subject matter the claimed discovery or invention must have both a specific and practical utility.

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?**

*Answer:* The current proposal does a good job of setting up technology neutral screening requirements that will prevent the patenting of ineligible subject matters such as genes as they exist in the human body. Accordingly, no more-specific listing of excluded subject matters is needed.

21C has further suggested that Congress may wish to consider adding an appropriately framed infringement exemption pertaining to non-commercial research undertaken for the purpose of understanding the claimed invention and experimenting on ways to improve on it.

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?**

*Answer:* Section 112 governs the nature of the disclosure and clarity of the claims required for an invention to be patented. It is neither necessary nor desired that inventors disclose everything they know about the field of the invention because patents are written to inform those of ordinary skill in the art to which the patent pertains how to make and use the invention. Inventors are neither required nor encouraged to tell those of ordinary skill what those of ordinary skill already know, but rather just what the inventors have done to distinguish their inventions from the “prior art.” Focusing the patent disclosure on what is new is helpful so that the USPTO and the public will not need to sift through extensive disclosures of old information in order to determine what the invention is. Properly framed patent claims further this objective, placing the public on notice of what the inventor regards to be his/her invention. This means that the determination of whether or not the court is properly applying Section 112 is highly fact and technology specific, and must be evaluated on case by case basis.

It is of course common for parties who have lost a case to complain that it was the fault of the court. But in the Section 112 area, there is well developed precedent as to what is required of a patent’s written description, what is required to enable a claimed invention, how an invention may be claimed, and what degree of definiteness is needed. Errors of law pertaining to these requirements are appealable and are considered by the Federal Circuit *de novo*.

In 21C’s view, the courts do a very good job in handling Section 112 challenges at all stages of the litigation, and the Federal Circuit pays close attention to Section 112 appeals. Because Section 112 disclosure requirements are necessarily technology specific, there always has been, and continues to be, an evolution of case law addressing new technologies. 21C continues to suggest that there should be further discussion of any changes to Section 112 proposed in draft legislation.

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

*Answer:* The solution to our current patent eligibility problems does not require any change to Section 112(f). As explained in my written testimony, the effects of the Section 112(f) changes in the current draft are unclear, and may produce a variety of unintended consequences. Accordingly, if any change to Section 112(f) is to be included in proposed legislation, it should continue to be discussed.

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

*Answer:* That is one of the concerns that has been voiced by many who have reviewed this provision, and it is a reasonable one. As mentioned above, inventors currently do not need to disclose all of the equivalents of each claimed element of their invention if those equivalents would be known or would be recognized from the inventor's disclosure to be equivalent by one of ordinary skill in the art. Under current language of 112(f), inventors are given the opportunity to frame their claims using "means plus function" language, in which case "such claim shall be construed to cover the corresponding structure, material or acts described in the specification, and equivalents thereof." To date, all existing patents and patent applications have been written with this option in mind. How the suggested Section 112(f) changes would impact its interpretation, its impact, if any, on how other paragraphs of section 112 would be interpreted, and whether the abrogation of the previous means plus function elections made by inventors would raise Constitutional due process and takings issues are unclear. These issues would benefit from ongoing discussion.

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?**

*Answer:* The proposed changes to Sections 100 and 101 pertain to what subject matter is eligible for patenting, not what subject matter is patentable. Section 101 relates only to "same invention" double patenting, which is a prohibition on obtaining two identically worded claims in two different patents. The current proposal would have no effect on "same invention" double patenting, which would continue to be disallowed.

By contrast, obviousness-type double patenting is a patentability doctrine that applies the obviousness test of Section 103 to determine whether the invention as claimed in a differently worded claim of the subject patent at issue, claims, nothing more than an obvious variation over what was claimed in the earlier reference patent. The USPTO currently applies the obviousness type double patenting doctrine rigorously during original examination and in post-issuance reexamination, reissue, supplemental examination and post grant review proceedings. Obviousness type double patenting issues are now routinely addressed by the USPTO in reexamination proceedings instituted at the requests of biosimilar or generic companies who wish to market new versions of existing drugs.<sup>1</sup> If not already handled by the USPTO, obviousness-type double patenting may be raised in defense of patent infringement proceedings. The current Section 100 and 101 proposals would have no effect on obviousness type double patenting issues or how they are handled by the USPTO and the courts.

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?**

*Answer:* 21C has not identified any potential Due Process Clause or Takings Clause problems stemming from the proposed changes to Sections 100 and 101. These changes simply restore the scope of patent eligible subject matter to its traditional scope before the Supreme Court's recent spate of Section 101 cases.

As mentioned above, some have suggested that the changes to Section 112(f), which might be construed to narrow the scope of protection for all existing patents, might raise both of these issues, which is one of the reasons 21C suggests that it be carefully studied if it is to be included in this series of reforms.

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<sup>1</sup> See for example, *In re Janssen Biotech, Inc., New York University*, (Appeal 2017-2357), \_\_\_\_\_ F3rd \_\_\_\_\_ (January 23, 2018).