

THE SEDONA CONFERENCE'S PATENT  
CONFERENCE (PART 2): PROMOTING  
INVENTION, ENTREPRENEURSHIP,  
ECONOMIC GROWTH,  
AND JOB CREATION

FRIDAY, JUNE 28, 2019

8:30 A.M. - 5:30 P.M.

COVINGTON

ONE CITY CENTER

850 TENTH STREET, NW

WASHINGTON, DC



Statement of Philip S. Johnson, Esq.

Before the

Intellectual Property Subcommittee of the  
Judiciary Committee of the  
United States Senate

on

“The State of Patent Eligibility in America: Part II”

June 5, 2019  
2:30 PM

## **Executive Summary of the Statement of Philip S. Johnson**

I wish to thank the Subcommittee for the opportunity for me to testify today on “The State of Patent Eligibility in America.”

I appear here today in my capacity as Chair of the Steering Committee of the Coalition for 21<sup>st</sup> Century Patent Reform, commonly referred to as “21C”. 21C is a diverse coalition of American manufacturers who rely on patents to protect their inventions, who develop and manufacture products protected by those patents, who license patents to and from others in furtherance of their business activities, and who, when necessary, assert their patents against infringers and/or defend against patents asserted against them. The Coalition for 21st Century Patent Reform represents companies from many different industry sectors and is led by a Steering Committee that includes 3M, Bristol-Myers Squibb, Eli Lilly, General Electric, Johnson & Johnson, Procter & Gamble, and United Technologies.

21C believes that a strong U.S. patent system is essential to American innovation and is the key to the future prosperity of our country. 21C views the importance of restoring high-quality, reliable U.S. patent protection to be a matter of national innovation policy that should be the principal interest not only of this Subcommittee, but of all three branches of our government. If done right, patent reforms will stimulate the private sector to invest in innovation, economic development, and job growth.

21C urges Congress to start by restoring patent eligibility to its traditional scope by closing judicially created loopholes that deny some of our best inventions the patent protection they deserve. Passage of the legislation based on the Tillis-Coons proposal (the “Proposal”)<sup>1</sup> to eliminate judicially-created exceptions to patent eligible subject matter, to preclude injecting *patentability* considerations into *patent eligibility* determinations, to clarify the utility requirement of Section 101, to require that in determining *patent eligibility* the claimed invention must be considered as a whole, and to instruct that Section 101 be construed in favor of eligibility, are steps forward that 21C strongly supports.

21C notes that in addition to provisions relating to patent *eligibility*, the Proposal suggests amending Section 112(f). Section 112(f) is a current *patentability* provision relating to the manner in which a patent claim should be construed if expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof. In 21C’s view amendment of Section 112(f) is not a necessary part of the solution to our current *patent eligibility* problem. Nonetheless, 21C suggests that if a change to Section 112(f) is proposed in draft legislation, it be studied further.

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<sup>1</sup> Senators Tillis and Coons, along with Chairman of the House IP Subcommittee Hank Johnson (D-GA), Ranking Member of the full House Judiciary Committee Doug Collins (R-GA) and Rep. Steve Stivers (R-OH) released this draft legislative text on May 22, 2019.

## **Statement of Philip S. Johnson**

Chairman Tillis, Ranking Member Coons, and distinguished members of the Subcommittee:

Thank you for providing me this opportunity to testify on “The State of Patent Eligibility in America.”

### ***Brief Introduction***

I appear here today in my capacity as Chair of the Steering Committee of the Coalition for 21<sup>st</sup> Century Patent Reform, “21C.”<sup>2</sup> 21C is a diverse coalition of American manufacturers who rely on patents to protect their inventions, who develop and manufacture products protected by those patents, who license patents to and from others in furtherance of their business activities, and who, when necessary, assert their patents against infringers and/or defend against patents asserted against them. The Coalition for 21st Century Patent Reform represents companies from many different industry sectors. 21C is led by a Steering Committee that includes 3M, Bristol-Myers Squibb, Eli Lilly, General Electric, Johnson & Johnson, Procter & Gamble, and United Technologies.

21C believes that a strong U.S. patent system is essential to American innovation and is the key to the future prosperity of our country. 21C believes the restoration of high-quality, reliable U.S. patent protection should be a principal objective of our national innovation policy. This objective should be a bi-partisan priority, which, if done right, will stimulate the private sector to invest in innovation, economic development, and job growth.

A major focus of 21C’s agenda is to restore patent eligibility to its traditional scope by closing judicially created loopholes that deny some of our best inventions, including inventions in the fields of artificial intelligence, software, diagnostic and biotechnology, the patent protection they deserve. These loopholes currently discourage inventors from pursuing research and development in areas that are critical to our future health, prosperity and wellbeing.

### ***Traditional Role of Section 101 in Defining Patent Eligibility***

Section 101 currently defines patent eligibility as follows:

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.

As referenced in *Diamond v. Chakrabarty*, 447 U.S. 303, 309 n.6 (1980), "This ... language was employed by P. J. Federico, a principal draftsman of the 1952 recodification, in his testimony regarding that legislation: '[U]nder section 101 a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man. . . .' Hearings on

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<sup>2</sup> A summary biography of my qualifications and experience is attached as Exhibit A.

H. R. 3760 before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess., 37 (1951)."

Section 101 defines the scope of patentable subject matter in two important respects. First, it limits what could be patented to inventions and discoveries that are the result of human intervention. It accomplishes this aim by specifying that only an "invention or discovery" which is a "process, machine, manufacture or composition of matter" or "improvement thereof" may be "eligible for patenting." Section 101 currently also requires that the invention or discovery be "new," but as the sponsors of the Proposal have appropriately recognized, this novelty requirement is redundant of the Patent Act's Section 102 novelty requirement and has caused problems because courts have misconstrued it to inject *patentability* issues into *patent eligibility* determinations. Nonetheless, the need still exists to ensure that patent eligible subject matter be limited to an inventions or discoveries of a "process, machine, manufacture or composition of matter, or "any improvement thereof," that have resulted from human intervention.

Section 101's second important function is to limit patent eligible subject only to inventions and discoveries that are "useful." Contrary to the suggestions of some, Section 101 has been very effective in this respect, and a robust body of administrative and judicial precedent has developed that has been the source of very little controversy. As interpreted and applied by the USPTO during patent examination, the "useful" eligibility requirement means that the patent application must include a credible assertion that the claimed invention or discovery has a "specific and substantial utility." The intention of this requirement is to ensure that to be patent eligible, the claimed invention or discovery must have an identified, practical utility. As the Court of Customs and Patent Appeals has stated:

Practical utility is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.

*Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).

### ***Origin of the Current Patent Eligibility Problem***

Patent cases seeking invalidation based upon Section 101 were virtually unheard of until about 2010 when the Supreme began changing patent eligibility policy in series of decisions culminating in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 134 S. Ct. 2347 (2014). Together with the decisions in *Bilski v. Kappos*, 561 U.S. 593 (2010), *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012) and *Ass'n for Molecular Pathology. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), the *Alice* decision sparked a firestorm of invalidity challenges based solely on patent eligibility grounds that soon engulfed not only software patents, but also medical diagnostics, biologics and many other types of invention that are critical to American innovation and global competitiveness.

Without any statutory basis, these recent Supreme Court decisions have created and/or expanded exceptions to Section 101's definition of patent eligible subject matter to prohibit the patenting of inventions or discoveries if they are "directed to" abstract ideas, natural phenomena, laws of nature and/or products derived from natural materials (such as isolated and/or purified substances). In 21C's view, these judicially created exceptions should be overruled by Congress because they are inappropriate, unworkable and unpredictable.

Judicially created exceptions to statutorily-defined patent eligible subject matter are inappropriate because our Constitution vests the responsibility for defining the scope of what subject matter may be patented in Congress alone.<sup>3</sup> Congress fulfilled this responsibility when it enacted 35 U.S.C. § 101, and has not ceded authority to the Supreme Court to re-write this definition or create whatever exceptions to it the Court might wish. But not only has the Supreme Court created such exceptions, experience has shown that it was ill suited to the task. As the Supreme Court itself recognized in its *Alice* decision:

At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. At some level, "all inventions ... embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept.

Yet the courts have not "tread carefully." And while the Supreme Court's exclusionary principles have not yet "swallow[ed] all of patent law," they have expanded them to the point that no one in the IP profession can now predict with certainty whether any given invention that relies in any way upon a law of nature, natural phenomenon, or abstract idea, or utilizes a naturally derived material, will be ultimately held patent eligible. Such amorphous and undefinable criteria have no place in our patent system.

Unfortunately, there are now many examples where the confusion created by the Supreme Court has resulted in meritorious discoveries and inventions being held patent ineligible. Two prominent ones are addressed in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015) ("[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.") and *Athena Diagnostics Inc. et al v. Mayo Collaborative Services*, \_\_\_ F.3d \_\_\_ (Fed. Cir. 2019) (methods for diagnosing neurological disorders by detecting antibodies to a protein called muscle specific tyrosine kinase found ineligible for patenting).

### ***Conceptual Framework for Patent Eligibility Reform***

21C believes that legislation is now needed to restore patent eligibility to its traditional role as a "coarse filter" on inventions eligible for patent protection and to ensure that Section 101 furthers

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<sup>3</sup> U.S. Constitution Article I, Section 8, Clause 8 provides that "The Congress shall have the Power. . . To promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."

our national innovation policies. Such legislation should be based on the guiding principles that were developed and refined with broad stakeholder input during the Senate IP Subcommittee's Roundtable proceedings, as follows:

- (1) Patent eligibility should not turn on the existence of related technology or the current state of the art. In other words, subject to meeting all other requirements of the patent statute, especially novelty, obviousness, enablement, written description, and definiteness, any useful invention should be eligible for protection regardless of whether it is new or old, conventional, known, or using other terms relevant to determining obviousness or anticipation.
- (2) When assessing the eligibility of patent claims, those claims must be construed as a whole, with each limitation in a claim given equal weight, and none dismissed or discounted as "routine," "known," "conventional," mere "data gathering," mere "post-solution activity," or the like. It is impermissible to carve up a claim into different parts and assess the eligibility of the parts of a claim separately, rather eligibility must consider the claimed invention as a whole.
- (3) Diagnostic and life science technologies should be eligible for patent protection per se, subject to meeting the other existing statutory requirements, and should not be considered a law of nature, natural phenomena, or otherwise patent ineligible subject matter.
- (4) Any reform to Section 101 should statutorily codify a definition . . . [of] patent eligibility. Any statutory exception(s) should not use the existing judicial exceptions of abstract ideas, laws of nature, or natural phenomena. Any statutory exceptions should be the sole and exclusive basis for excluding subject matter from eligibility and may not be expanded upon by courts. Any definition of eligible subject matter should be adaptive to include new technologies not yet invented.

### ***Proposed Statutory Language Pertaining to Patent Eligibility***

21C congratulates the sponsors of the Proposal for presenting legislative language that would rectify our current Section 101 problem. This language (with the exception of proposed amendments to Section 112 which are discussed later) is reproduced below:

#### **Section 100:**

(k) The term "useful" means any invention or discovery that provides specific and practical utility in any field of technology through human intervention.

#### **Section 101:**

(a) Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(b) Eligibility under this section shall be determined only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation.

### **Additional Legislative Provisions:**

[1] The provisions of section 101 shall be construed in favor of eligibility.

[2] No implicit or other judicially created exceptions to subject matter eligibility, including “abstract ideas,” “laws of nature,” or “natural phenomena,” shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated.

[3] The eligibility of a claimed invention under section 101 shall be determined without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102, 103, or 112 of this title.

While the Subcommittee has made it clear that additional refinements to this language are likely, 21C strongly supports this approach, and looks forward to working further with the Subcommittee on any improvements or clarifications that may be needed to achieve its enactment.

### ***Provision-by-Provision Comments on the Proposal***

#### *Section 100(k)*

The addition of Section 100(k) appropriately proposes to provide an explicit definition of the term “useful” as it is used in Section 101:

(k) The term “useful” means any invention or discovery that provides specific and practical utility in any field of technology through human intervention.

It has long been recognized that to meet Section 101’s requirement, patent eligible subject matter must be “useful.”<sup>i</sup> This utility requirement derives from the Constitution, which authorizes Congress to provide exclusive rights to inventors for their inventions and discoveries which advance the progress of the “useful arts.” In determining whether a claimed invention is “useful” within the meaning of Section 101 the USPTO and the courts have long required patent applications to disclose “specific”<sup>ii</sup> and substantial<sup>iii</sup> utilities for the inventions claimed. As the Court of Customs and Patent Appeals has stated:

Practical utility is a shorthand way of attributing “real-world” value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.

*Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980). By requiring that for an invention or discovery to be “useful” it must provide “a specific and practical utility” this



definition conforms both with existing judicial precedent and the USPTO's guidance on utility that has long been applied for examining patent applications under Section 101.<sup>4</sup>

By further specifying that that utility may be in "any field of technology through human intervention" the definition makes explicit what was previously implicit in Section 101, both that human intervention must be involved and that the utility must be one involving the useful arts (per the Constitution's authorization).<sup>5</sup>

### *Section 101*

The proposed amendment of Section 101 appropriately drops the word "new" from the current text of Section 101(a), and adds new paragraph (b), as follows:

**Section 101:**

(a) Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(b) Eligibility under this section shall be determined only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation.

21C also strongly supports these proposed changes. As mentioned above, the term "new" as previously used in the first paragraph caused considerable confusion, inappropriately injecting the patentability criteria of novelty, which is extensively defined in Section 102, into patent eligibility determinations which should have nothing to do with novelty. The second paragraph expressly forbids the recent court practice of discounting or disregarding certain claim limitations when determining patent eligibility, restoring the time-honored rule that all claim limitations must be considered and credited when considering the claimed invention as a whole. This provision remains of critical importance in view of the Supreme Court's demonstrated propensity for discounting important claim elements.

### *Additional Legislative Provisions*

21C also strongly supports additional legislative provisions [1], [2] and [3], as set forth below:

[1] The provisions of section 101 shall be construed in favor of eligibility.

[2] No implicit or other judicially created exceptions to subject matter eligibility, including "abstract ideas," "laws of nature," or "natural phenomena," shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated.

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<sup>4</sup> See MPEP Section 2107 (II)(A) & (B).

<sup>5</sup> Going forward, the Subcommittee may wish to consider whether it might be preferable to replace "any field of technology" with the Constitutional phrase "in the useful arts," as some have suggested that "technology" is a term that is susceptible to several different meanings.

[3] The eligibility of a claimed invention under section 101 shall be determined without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102, 103, or 112 of this title.

The first of these provisions is needed because the purpose of Section 101 is to act as a course filter to favor eligibility as long as the recited requirements are met. The second and third of these provisions, as discussed above, are needed to prohibit the courts from creating and applying exceptions to patent eligible subject matter that are not authorized by statute, and from improperly injecting patentability considerations into patent eligibility determinations.

### *Practical Effects of these Amendments*

A practical effect of these clarifications will be to ensure that naturally occurring materials and compositions as they exist in nature, including human genes, will remain patent ineligible. In particular, and in contrast to the assertions of the ACLU and others, the Proposal would not “authorize patenting products and laws of nature, abstract ideas, and other general fields of knowledge,” nor would it “permit patenting of human genes and naturally-occurring associations between genes and diseases.” These would remain patent ineligible because they are not “inventions or discoveries,” did not result from “human intervention,” and do not have “specific and practical utility in any field of technology.”

By contrast, life sciences inventions in the diagnostics area should qualify as patent eligible because they are the result of human intervention and do have a specific and practical utility in the field of medicine. Isolated, purified or modified compositions *per se* may not be patent eligible if they have no known utilities, but may be incorporated as claimed elements in methods or compositions that constitute discoveries or inventions which, when viewed as a whole, are the result of human intervention and do have a specific and practical utility in a field of technology.<sup>6</sup>

Purely mental activities, the law of gravity, marriage proposals and other such fanciful hypotheticals would fail to qualify as patent eligible because they are not a “process, machine, manufacture, or composition of matter, or any improvement thereof” and/or “because they fail to provide a specific and practical utility in any field of technology through human intervention” and thus fail to meet the Proposal’s definition of being “useful”.

Fundamental scientific, economic or commercial principles and pure mathematical formulas would similarly fail to qualify as patent eligible because they do not meet the requirements of being an “invention or discovery” that is “a process, machine, manufacture, or composition of matter, or any improvement thereof” or of having “a specific and practical utility in any field of technology through human intervention.”

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<sup>6</sup> Exceptions that are based entirely upon public policy considerations, such as the existing statute that prohibits (and will continue to prohibit) the patenting of “human organisms,” will not be disturbed.

Of course, all of the above hypotheticals would likely also be deemed unpatentable under Section 102 for lacking novelty, by Section 103 as obvious, and/or (c) by Section 112, as not being sufficiently described in patent specification to enable the full breadth of any claim directed solely to them.

### ***Proposal to Amend Section 112(f)***

In addition to its proposals relating to patent eligibility, the Proposal suggests amending Section 112(f). In 21C's view amendment of Section 112(f) is not a necessary part of the solution to our current *patent eligibility* problem. However, to the extent such reform needs to address issues related to claiming requirements, Section 112, rather than Section 101 is the place to do so.

Section 112(f) is currently a *patentability* provision relating to the manner in which a patent claim should be construed if expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof. The proposed changes to Section 112(f) as it is currently written are shown in ~~strikeout~~ and ~~redline~~ below:

#### ~~(f) Element in claim for a combination.~~ **Functional Claim Elements**—

An element in a claim ~~for a combination may be~~ expressed as a ~~means or step for performing~~ specified function without the recital of structure, material, or acts in support thereof, ~~and such claim~~ shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

As originally passed in 1952, Section 112(f) was intended to create a safe harbor for combination claims within which inventors could describe elements as a means or step for performing one or more specified functions without needing to recite the structure, material or acts needed to accomplish them. Although the rationale behind the proposed amendment is unclear, its intent appears to alter the claim construction process to focus on construing elements of a claim on an element-by-element basis rather than on the claim as a whole, and to construe each element “to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” By dropping the former reference to a “means or step for performing” a specified structure, the amendment appears to broaden the provision to cover all elements of all existing and future patent claims that contain at least one element that is “expressed as a specified function” without also reciting some structure, material or acts “in support thereof.” Accordingly, inventors will no longer have the option of deciding whether or not to invoke the operation of Section 112(f) by deciding whether to phrase the claim as a “means or step for performing” a specified function, and even if they elected not to in the past, will henceforth be treated as if they had.

Amendment of Section 112(f) is a problematic because the law pertaining to other related provisions in Section 112 is necessarily technology specific, making the differential impacts of the proposed changes across different industries difficult to predict. Thus far, reaction to this proposed change within the technology sector has been mixed at best. As one commentator

remarked, “to call it alarming would be an understatement,” as in his opinion this change “would sharply and seemingly limit the property rights of all technology patents.”<sup>7</sup>

In the biopharmaceutical industry for some inventions the only way to obtain commercially meaningful patent protection may be to seek genus claims that recite functional elements or steps. But will the application of new Section 112(f) mean that the enablement and written descriptions requirements of Sections 112(a) will now be judged against the full scope of a claim construed under new Section 112(f), including the “equivalents” of the “the corresponding structure, material, or acts described in the specification”? While some contend that the Section 112(f) proposal will not narrow such genus claims because the proposed language must necessarily take precedent over the requirements of Sections 112(a) as to the equivalents encompassed in Section 112(f), others fear that the effect of the amendment would be the opposite. Their fear is that the proposal may limit patent coverage to the individual species disclosed in the application even when under current law their number and breadth would support the full scope of the genus claim, and that application of the existing requirements of Sections 112(a) as to infringing embodiments within the claimed genus may result in the denial of otherwise well-deserved patent protection. If so, further language would be needed to negate that possibility by requiring such Section 112(f) equivalents to be disregarded for Section 112(a) purposes.

Changes of this nature, which potentially implicate all existing and future patent claims, may also raise secondary concerns about their effects on the interpretations of other related patentability provisions. And while not all elements will be construed under Section 112(f), there will also be some ambiguity in determining whether the language of a claim element is or is not “expressed as a specified function,” as many recited elements inherently disclose their functions. For example, are “pharmaceutically acceptable salts” (which are frequently mentioned in drug composition claims) salts that are described as a “specified function” by the use of the adjectives “pharmaceutically acceptable”?

In the software/high technology industries, complaints have been made that functional claiming in these technologies provides unwarranted breadth to undeserving inventions in that field. In particular, critics have argued that genus claims are too often allowed whose breadth is not properly circumscribed in the patent disclosure, and that a rule is needed that will force all existing and future patent claims to be limited to the patent’s expressly disclosed embodiments. But this problem has already been addressed by the recent *en banc* decision in *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015), which addresses this functional claiming concern by holding that when a claim term lacks the word “means,” the presumption against employing Section 112(f) will be overcome “if the challenger demonstrates that the claim term fails to ‘recite sufficiently definite structure’ or else recites ‘function without reciting sufficient structure for performing that function’.”

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<sup>7</sup> Greenspoon, Robert P., “Congress’ Section 101 Fix Would Create a 112(f) Problem.” IP Watchdog, May 28, 2019, available at [www.ipwatchdog.com/2019/05/28/congress-section-101-fix-create-112f-problem/id=109766/](http://www.ipwatchdog.com/2019/05/28/congress-section-101-fix-create-112f-problem/id=109766/) ; see also Laundau, Josh, “Senators Tillis and Coons Draft Fundamentally Flawed Section 101 Legislation,” May 28, 2019 (“While the change would remove any suggestion that the magic words “means for” are meaningful, it simply isn’t a significant change. It would do absolutely nothing to combat abstract and overbroad patents that current case law doesn’t already do.”), available at [www.patentprogress.org/2019/05/23/senators-tillis-and-coons-draft-fundamentally-flawed-%c2%a7-101-legislation%ef%bb%bf/](http://www.patentprogress.org/2019/05/23/senators-tillis-and-coons-draft-fundamentally-flawed-%c2%a7-101-legislation%ef%bb%bf/)

Under the circumstances, 21C suggests that Section 112 reform continue to be studied if it is included in any draft legislation. When amendments to Section 112 are considered, 21C suggests that they be made the subject of a separate roundtable process similar to the one used by the Subcommittee for Section 101, so that appropriate language can further be developed and the ramifications of any future changes be more fully understood. At that time, the Subcommittee will have the opportunity to agree on guiding principles within which clear and meaningful legislative language can be formulated, and to appropriately weigh the impacts that such legislation would have on different industries.

## ***Conclusion***

21C appreciates the opportunity to submit written testimony on these important topics and to have Phil Johnson, the Chair of its Steering Committee, appear at the hearing scheduled for June 5, 2019 to answer any questions the Subcommittee may have concerning the current state of patent eligibility and the Proposal to fix our current patent eligibility problem. As explained above, 21C strongly supports the approach taken by the Proposal to add new paragraph 100(k), to amend Section 101, and to add the Proposal's three other legislative provisions. 21C looks forward to continuing to work with the Subcommittee to achieve enactment of effective patent eligibility legislation that will stimulate the private sector to invest in innovation, economic development, and job growth.

## Exhibit A



PHILIP S. JOHNSON

Phil is the principal of Johnson-IP Strategy and Policy Consulting, which he founded after his retirement in February 2017 as Senior Vice President - Intellectual Property Policy & Strategy of Johnson & Johnson – Law Department. He is currently Chair of the Steering Committee of the Coalition for 21st Century Patent Reform, a Steering Committee Member and Co-Chapter Editor of the Sedona Conference WG10 biopharmaceutical patent litigation project, and a member of the board of the Monell Chemical Senses Center. Prior to April of 2014, he was Senior Vice President and Chief Intellectual Property Counsel of Johnson & Johnson where he managed a worldwide group of about 270 IP professionals, of whom over 100 were patent and trademark attorneys.

Before joining Johnson & Johnson in 2000, Phil was a senior partner and co-chair of IP litigation at Woodcock Washburn in Philadelphia. During his 27 years in private practice, Phil counseled independent inventors, startups, universities and businesses of all sizes in all aspects of intellectual property law. His diverse practice pertained to advances in a wide variety of technologies, including pharmaceuticals, diagnostics, medical devices, consumer products, semi-conductor fabrication, automated manufacturing, materials and waste management. During his time in private practice, Phil served as trial counsel in countless IP disputes, including cases resolved by arbitration, bench trials, jury trials and appeals to the Federal Circuit Court of Appeals, many of which resulted in reported decisions.

During his tenure at Johnson & Johnson, Phil served terms on the Medical Device & Diagnostics and Pharmaceutical Group Operating Committees responsible for managing J&J's many businesses in these fields, while also serving on the senior

management team responsible for J&J's legal organization, which then comprised over 450 attorneys located in 70+ locations in 35+ countries.

Phil has previously served as the Chair of the Board of American Intellectual Property Law Education Foundation, as President of the Intellectual Property Owners Association, as President of INTERPAT, as President of the Association of Corporate Patent Counsel, as President of the Intellectual Property Owners Education Foundation, as Chair of PhRMA's IP Focus Group and as Board Member of the American Intellectual Property Law Association.

Phil has frequently testified before both the House and Senate Judiciary Committees about patent law reform, abusive patent litigation practices and, more recently, "Sovereign Immunity and the Intellectual Property System." Phil served as a member of Chief Judge Michel's Advisory Council on Patent Reform and was recognized in the Congressional Record as a member of the Minority Whip Jon Kyle's "Kitchen Cabinet" for the America Invents Act ("AIA"). Thereafter, Phil served as IPO's representative on the ABA-AIPLA-IPO committee of six experts ("COSE") formed at the Director's request to propose regulations to the USPTO for implementing the PGR-IPR post-grant proceedings created by the AIA.

Phil co-authored "Compensatory Damages Issues In Patent Infringement Cases, A Pocket Guide for Federal District Court Judges," and its 2017 edition, "Compensatory Damages Issues in Patent Infringement Cases," both published by the Federal Judicial Center, and has served that Center as a faculty member on its IP-related judicial education programming. Phil was featured in the Landslide Publication March/April 2013 issue. Phil also authored "The America Invents Act on Its Fifth Anniversary: A Promise Thus Far Only Partially Fulfilled," (9/15/2016), and "A Look Back at the Legislative Origin of IPRs" (9/19/2017), both published in IP Watchdog.

Phil's awards include the Woodcock Prize for Legal Excellence (1997); the New Jersey Intellectual Property Law Association's Jefferson Medal (2013); the Philadelphia Intellectual Property Association's Distinguished Intellectual Property Practitioner award (May, 2017), induction into the international IP Hall of Fame by the IP Hall of Fame Academy (June, 2017) and the Intellectual Property Owners Association "Carl B. Horton President's Distinguished Service Award" (September, 2017).

Phil received his Bachelor of Science degree, *cum laude* with distinction in biology from Bucknell University, and his J.D. degree from Harvard Law School.

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<sup>i</sup> MPEP Section 2107.01 provides:

## I. SPECIFIC AND SUBSTANTIAL REQUIREMENTS

To satisfy [35 U.S.C. 101](#), an invention must be “useful.” Courts have recognized that the term “useful” used with reference to the utility requirement can be a difficult term to define. *Brenner v. Manson*, 383 U.S. 519, 529, 148 USPQ 689, 693 (1966) (simple everyday word like “useful” can be “pregnant with ambiguity when applied to the facts of life.”). Where an applicant has set forth a specific and substantial utility, courts have been reluctant to uphold a rejection under [35 U.S.C. 101](#) solely on the basis that the applicant’s opinion as to the nature of the specific and substantial utility was inaccurate. For example, in *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980), the court reversed a finding by the Office that the applicant had not set forth a “practical” utility under [35 U.S.C. 101](#). In this case the applicant asserted that the composition was “useful” in a particular pharmaceutical application and provided evidence to support that assertion. Courts have used the labels “practical utility,” “substantial utility,” or “specific utility” to refer to this aspect of the “useful invention” requirement of [35 U.S.C. 101](#). The Court of Customs and Patent Appeals has stated:

Practical utility is a shorthand way of attributing “real-world” value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.

*Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).

Practical considerations require the Office to rely on the inventor’s understanding of his or her invention in determining whether and in what regard an invention is believed to be “useful.” Because of this, Office personnel should focus on and be receptive to assertions made by the applicant that an invention is “useful” for a particular reason.

<sup>ii</sup> MPEP 2107.01 A states:

### A. Specific Utility

A “specific utility” is *specific* to the subject matter claimed and can “provide a well-defined and particular benefit to the public.” *In re Fisher*, 421 F.3d 1365, 1371, 76 USPQ2d 1225, 1230 (Fed. Cir. 2005). This contrasts with a *general* utility that would be applicable to the broad class of the invention. Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has “useful biological” properties, would not be sufficient to define a specific utility for the compound. See, e.g., *In re Kirk*, 376 F.2d 936, 153 USPQ 48 (CCPA 1967); *In re Joly*, 376 F.2d 906, 153 USPQ 45 (CCPA 1967). Similarly, a claim to a polynucleotide whose use is disclosed simply as a “gene probe” or “chromosome marker” would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. See *In re Fisher*, 421 F.3d at 1374, 76 USPQ2d at 1232 (“Any EST [expressed sequence tag] transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses.... Nothing about [applicant’s] seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the [ ] application or indeed from any EST derived from any organism. Accordingly, we conclude that [applicant] has only disclosed general uses for its claimed ESTs, not specific ones that satisfy [§ 101](#).”). A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a “useful” invention may arise from what has been disclosed by the applicant. *Knapp v. Anderson*, 477 F.2d 588, 177 USPQ 688 (CCPA 1973).

<sup>iii</sup> MPEP 2107.01(B) states:

**B. Substantial Utility** “[A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the ‘substantial’ utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public.” *Fisher*, 421 F.3d at 1371, 76 USPQ2d at 1230. The claims at issue in *Fisher* were directed to expressed sequence tags (ESTs), which are short nucleotide sequences that can be used to discover what genes and downstream proteins are expressed in a cell. The court held that “the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of [applicant’s] research



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effort, but only tools to be used along the way in the search for a practical utility.... [Applicant] does not identify the function for the underlying protein-encoding genes. Absent such identification, we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.” *Id.* at 1376, 76 USPQ2d at 1233-34). Thus a “substantial utility” defines a “real world” use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a “substantial utility” define a “real world” context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a “real world” context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use and, therefore, do not define “substantial utilities”:

- (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
- (B) A method of treating an *unspecified* disease or condition;
- (C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
- (D) A method of making a material that itself has no specific, substantial, and credible utility; and
- (E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

Office personnel must be careful not to interpret the phrase “immediate benefit to the public” or similar formulations in other cases to mean that products or services based on the claimed invention must be “currently available” to the public in order to satisfy the utility requirement. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 USPQ 689, 695 (1966). Rather, any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a “substantial” utility.