Questions for Bob Armitage
IP Consultant (former General Counsel of Eli Lily)

1. **Bob, thank you for all your work on this issue over the years. From the beginning of our roundtable process you were advocating making tweaks to Section 112(f) as an alternative way to address the concerns some have regarding the issuance of overbroad software patents. As you know, our proposal attempts to do just that. Can you explain to us very briefly your thought process on why a 112(f) fix is a necessary and appropriate compliment to any 101 reform?**

RESPONSE: There should be—when a patent law is boiled down to its essence—only four fundamental reasons why patent should be denied to an inventor. These are that the patent claim setting out the subject matter that the inventor is seeking to protect is not:

(1) *sufficiently different* from technology already in existence (*i.e.*, "prior art") (35 U.S.C. § 102/§ 103);

(2) *sufficiently definite* in establishing what does or does not fall within the boundaries of the claim (35 U.S.C. § 112(b));

(3) *sufficiently disclosed* in the patent's specification given the breadth of protection being sought (35 U.S.C. § 112(a)), or;

(4) *sufficiently delineated* in terms of a process, machine, manufacture, or composition of matter that affords a specific and substantial contribution to a "useful art," *i.e.*, through a practically useful application of technology to an area of human endeavor (35 U.S.C. § 101).

The challenge of the Subcommittee's present efforts is to adequate accommodate the wide spectrum of interests affected by the patent system in a manner that reflects these four constraints on an inventor's ability to patent—and keeps them in the necessary balance so that a not-too-much and a not-too-little patent law operates unequivocally to promote progress in useful arts.

No one quibbles much that a patent claim that would include within its scope subject matter that differs in only trivial respects from already existing technology would hardly to serve to promote progress in useful arts. Similarly, an inventor that did not employ adequate precision in the language used to define the "metes and bounds" of protection under its patent so that the public might have reasonable certainty as to where the boundaries of the claim end, should not expect that that its patent claims would be respected.

In some respects, these *sufficiently different* and *sufficiently definite* requirements for securing a valid patent claim produce less of a policy dilemma in legislating a patent law than the *sufficiently disclosed* and *sufficiently delineated* requirements. More problematically, these two requirements, albeit

conceptually independent requirements, almost inevitably become commingled in discussions of patent policy and patent system operation—including in opinions of the Supreme Court.

Even for patents where it is clear that the subject matter being claimed is highly inventive and the boundaries of protection being sought are clear-cut, the scope of protection under a claim can be so expansive—namely, any subject matter that falls within a functional definition for a crucial element of the invention being claimed—that no court could stand aside and allow such a claim to be enforced against an accused infringer. This was the precise issue faced twice by the Supreme Court, first in *O'Reilly v. Morse* and again in *Halliburton v. Walker*. In both cases the *subject matter for which protection was being sought* fell within the bounds of eligible subject matter, but the breadth of protection under the claims would have been way over the top of what any patent statute should have permitted.

The eighth claim of the *Morse* patent was a "single element" or "single means" claim in which the claim would have encompassed to any electromagnetic device capable of communicating intelligible information from a distance. *Halliburton* used similar functional terminology to define the scope of protection in a claim consisting of a "combination" of discrete elements, employing functionally characterizing terminology for an element of the claim that was crucial to the novelty of the combination as a whole.

This type of functional recitation of an element in a claim—a function to be performed, a result to be achieved, a property to be exhibited, or a mechanism through which the element acts—if permitted to define a valid scope of protection for a patent claim, can seriously undermine the operation of the patent system as a tool to promote useful arts. A later inventor, having invented its own new and non-obvious device, might be able to readily discern from reading patents previously sought that its new device had never before been described in earlier patent filings of other inventors. However, such an inventor would have a more difficult time knowing if its new device might infringe a patent if the test for infringement was whether such a new new device somehow might perform a function, achieve a result, exhibit a property, or act through a mechanism that was the subject of a claim in an earlier patent filing of another inventor.

This is not just a theoretical concern over functional claiming. Examples of the problems arising from a patent effectively claiming a "mechanism of action" can be found across the useful arts. These concerns do not just arise for software-implemented or other computer-related inventions.

Claims of such potentially stunning breadth have been sought—and secured—in all areas of technology, including the biopharma arena. Eli Lilly and Company, as an example, was sued under U.S. patent 6,410,516 with claims directed to "NF-κB induction" processes. The patent was issued with a thicket of over 200 separate claims. Lilly was sued for infringement of this patent on the day that it issued on June 25, 2002.

It took eight years from the day the patent issued before the patent was finally invalidated as having only *insufficiently disclosed* claims under the "written description": requirement in 35 U.S.C. § 112(a). *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc). Lilly's price tag for defending against the invalidity allegations under this meritless patent ran into eight figures—a truly staggering investment of time and money to be able to dispense with the claims of just one patent.[1]

Imagine the burden of patents of this ilk were to issue in the dozens, much less hundreds, much less thousands—among the 300,000 patents now being issued annually by the United States Patent and Trademark Office. The magnitude of such a challenge can be seen from just the first of the patent's 203 functionally defined claims reads:

> *1. A method for inhibiting expression, in a eukaryotic cell, of a gene whose transcription is regulated by NF-κB, the method comprising reducing NF-κB activity in the cell such that expression of said gene is inhibited.*

This is a single-step claim that under today's patent law is not self-evidently subject to 35 U.S.C. § 112(f). Nominally, at least, the claim is not subject to § 112(f) because it is not a "claim to a combination" of two or more steps.

Had this claim been subject to § 112(f), Lilly would not have been able to invalidate this claim under § 112(a) for lack of an adequate "written description"—which is what Lilly was able to do only after 8 years of patent litigation. Indeed, under the remedial nature of § 112(f), Ariad's claim 1 would have been valid—and would have provided protection at least to the extent that the Ariad patent described specific means for reducing NF-κB activity in a cell.

However, had the claim been both valid and so limited, the 8-year, multi-million-dollar legal defense that Lilly undertook to invalidate the claims of the Ariad patent would have been compressed to, at most, *a summary judgment ruling of non-infringement*. Lilly might not have even bothered to contest the validity of

[1] A fuller discussing of this patent and Lilly's 8-year odyssey to invalidate its claims can be found at https://republicans-judiciary.house.gov/wp-content/uploads/2016/02/Armitage-Testimony-1.pdf.

the claims because the Ariad patent nowhere described the means that Lilly allegedly employed to infringe the patent.

Indeed, it is far more likely that—had § 112(f) applied to both *validate* and *limit* Ariad's functionally defined claims, there would have been no lawsuit brought against Eli Lilly and Company. No law firm might have been available to bring an infringement action against Lilly given the Rule 11 bar to bringing lawsuits containing frivolous allegations of patent infringement.

I have no doubt whatsoever that the U.S. patent system would have better served both Ariad and Lilly had amendment to 35 U.S.C. § 112(f) proposed to accompany the § 101 reforms now before this Subcommittee been part of the patent law in 2002. Ariad would have secured a valid patent with claims extending to the specific means it disclosed in its patent and any equivalents thereto. Lilly would have been spared years of litigation and its multi-million-dollar defense efforts. This is what I call a win-win-win outcome. Not only do both Ariad and Lilly gain relative to the litigation outcome, but the public gains as well when the patent system has such a self-correction mechanism to address claims that are overly broad.

The connection between the proposed § 101 reforms and the need for § 112(f) reform is self-evident from the chronology at work in the Ariad-Lilly litigation. Lilly's final success at the Federal Circuit came on March 22, 2010; the Supreme Court's decision in *Bilski v. Kappos* was rendered three months later—on June 28, 2010—with the Supreme Court decisions in *Mayo*, *Myriad*, and *Alice* to follow.

Were Lilly to be faced with an infringement lawsuit on the Ariad patent today, it would have in its defensive arsenal the opportunity to pursue a Rule 12(b)(6) motion to have all 203 claims of the Ariad patent struck down under the Supreme Court's *Mayo/Alice* two-part test. There would be a near certainty that an infringement lawsuit brought against Lilly would be over almost as soon as the infringement complaint was filed. That outcome, of course, assumes that the Ariad patent would even have issued in the first place under the USPTO's implementation of the *Mayo/Alice* two-part test.

Coupling the abrogation of the *Mayo/Alice* two-part test with the imposition of the proposed § 112(f) amendment would allow Congress to address both the stated policy concerns of the Supreme Court in *Alice* for imposing its "implicit exception" jurisprudence and the practical implications in patent litigation when an Ariad-like patent has been issued. It would allow the reading of a patent to provide with far greater precision an indication of the scope of protection under the patent. Equally importantly, it is a *remedial* and *self-correcting* provision that both secures for patent owners a greater prospect that claims will be

construed as valid under § 112(a). The concern of the Supreme Court that patent should not preempt access to basic tools of scientific and technological work would be mooted.

Thus, even if the proposed § 112(f) amendment had no applicability whatsoever for software-related or computer-implemented inventions, it would be worthwhile and fully justified as an essential adjunct to remediation of the Supreme Court's § 101 jurisprudence. However, the software arena is where this provision may well to its greatest good. At best, the understanding of § 112(a)'s "written description" requirement for "software" patents is a judicial work in progress. There is no analogue to the *Ariad* decision in the software-related arts.

If the § 101 hurdle to securing valid patent rights is to be lowered by abrogating the "implicit exception" jurisprudence, it is essential for Congress to assure that the remaining hurdles stand tall enough. This includes the § 112(a) disclosure requirement that would invalidate overly broad claims absent the ability of proposed § 112(f) to protect them from such invalidation by confining their breadth to the scope of the supporting disclosure laid out in the patent.

2. What do you think about our proposed 112(f) language? Do you believe it strikes the appropriate balance?

What the Subcommittee has proposed is perfect. It introduces no new words of substance into the statute. All of the existing § 112(f) law developed since 1952 would be preserved. It amends the statute only be removing limitations. By removing "for a combination," amended § 112(f) will allow single-element claims to fall within its remedial provisions. By removing "means or step for," the Federal Circuit's dueling presumptions of applicability/inapplicability of § 112(f) in *Williamson v. Citrix* will be mooted and its applicability will be determined under the normal canons of claim construction that otherwise apply to all claims. Seldom can the effects of a statutory change be summarized in a manner that is this clear and this concise.

That said, the text has come under criticism precisely because of its elegant and surgical nature—only excising potential limitations on its applicability. If the Subcommittee determines that it needs to address the criticisms that the amended § 112(f) is not sufficiently "essay-like" by more completely stating the applicable law that has been in effect since 1952, then I would recommend to the Subcommittee that it consider an more complete statement of the applicable law with the statute itself.

Possible "essay-like" language for incorporation into § 112(f) could include:

> *"(f) REQUIRED CLAIM CONSTRUCTION.—An element in a claim expressed as a specified function, without the recital of structure, material, or acts in support thereof, shall be construed for the purposes of this chapter as though the claim had further recited the corresponding structures, materials, or acts described in the specification as limitations to the claim and shall be deemed otherwise to cover only such structures, materials, or acts and the equivalents thereof. An element shall not be regarded as being expressed as a function based on terminology referencing an established category of structures, materials, or acts."*

The above version of amended § 112(f) would make five substantive changes to the text of § 112(f) as originally enacted under the 1952 Patent Act:

(A) The limitation to "combination" claims is removed. Amended § 112(f) applies to both single-element or single-means claims as well as claims that are drafted as a combination of discrete elements (*e.g.*, process claims that contain multiple discrete steps to be performed).

(B) The phrase "a means or step for performing" is removed. This phrase has been the basis for presumptions of the applicability or inapplicability of § 112(f) based on the presence or absence of the words "means for" or "step for" in a claim. The elimination of this phrase removes the statutory basis for decisions of the courts imposing such presumptions,[2] allowing all claim elements to be given their plain meaning as they would be understood by a person skilled in the art in a presumption-free manner.

(C) If a claim element is subject to amended § 112(f), the claim as limited under § 112(f) is the interpretation of the claim that would apply for the purposes of determining the patentability of the claim under chapter 10 (Patentability of Inventions) of title 35, United States Code. It is the § 112(f)-mandated construction of the claim element that is used to determine if the

[2] The current form of the Federal Circuit's presumptions of applicability/inapplicability are explained by the court in *Williamson v. Citrix Online, LLC,* 792 F. 3d 1339, 1349 (Fed. Cir. 2015). The Federal Circuit removed a "strong presumption" of inapplicability of § 112(f) absent the words 'means for"/"step for" appearing in the claim element and replaced it with the following: "The standard is whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure. … When a claim term lacks the word 'means,' the presumption can be overcome and [§ 112(f)] will apply 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.' … The converse presumption remains unaffected: 'use of the word "means" creates a presumption that [§ 112(f)] applies.'"

claim constitutes patent-eligible subject matter under 35 U.S.C. § 101, is novel and non-obvious under 35 U.S.C. § 102/§ 103, is sufficiently disclosed under 35 U.S.C. § 112(a),[3] and is sufficiently definite under 35 U.S.C. § 112(b).[4]

(D) For purposes other than patentability, *i.e.*, for determining whether the claim has been infringed, under amended § 112(f), the claim element for which § 112(f) is applicable is deemed to cover the corresponding structures, materials, or acts described in the specification of the patent and the equivalents thereof.

(E) The second sentence of amended § 112(f) is new and codifies a longstanding principle that a claim element cannot be regarded as functional in character if the language in the claim element references an established category of structures, materials, or acts. Claim language of this type is typically used in claim elements that are not crucial to the novelty or non-obviousness of the claim.[5]

3. Are there any other potential changes you think we should consider pairing with our 101 fix, like an experimental use exception for example?

Yes. There are several additional reforms that would be desirable to producing a package of ancillary legislative changes that would either address expressed concerns of the Supreme Court over the operation of the U.S. patent system (a "research use" exception to infringement would be one such change) and those concerned that the patent system can overreach legitimate bounds of protection that can advance progress in useful arts. What follows is a catalog of possible adjuncts or substitutes for language in the draft bill.

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[3] A claim element that is limited to corresponding structures, materials, or acts disclosed in the specification of a patent would ordinarily meet the "written description" requirement under 35 U.S.C. § 112(a).

[4] Nothing in amended § 112(f) precludes the United States Patent and Trademark Office from affording a claim element that may be subject to § 112(f) a broadest reasonable interpretation during patent examination. The practice of patent examiners of interpreting a claim element that might be subject to § 112(f) as encompassing all possible means for carrying out a function recited in the claims would be unaffected under amended § 112(f). If § 112(f) is determined by the examiner to be applicable to a claim element, the patent applicant could be required to identify the corresponding structures, materials, or acts to which the § 112(f) would limit the claim in order to establish that the claim met the requirements for patentability, *i.e.*, novelty and non-obviousness over prior art and sufficient definiteness.

[5] An example of commonly used terminology in claims, where a term that both identifies a function and references an established category of structures, is "pharmacologically acceptable salt form." Such terminology is often used in connection with the discovery of a chemical compounds, such that the reference to its salt forms is not a crucial limitation in a claim that is inclusive of the salt forms. *i.e.*, the novelty and non-obviousness of such a claim will typically depend exclusively on the inventiveness of the chemical compound.

The specific additions or substitutions, besides the § 112(f) amendment discussed above, that are recommended for consideration fall into the following five areas:

(1) RESEARCH USE EXEMPTION:

In section 271, insert at the end:
"(j) Notwithstanding subsections (a) and (g), it shall not be an act of infringement to make or use a claimed invention for experimental purposes to discern or discover—
"(1) the validity or scope of protection of a patent for the claimed invention;
"(2) any feature, property, characteristic, advantage, or disadvantage of the claimed invention;
"(3) any method of making or using the claimed invention;
"(4) any alternative to, improvement to, or substitute for the claimed invention."

The new subsection (j) is added to § 271 that would prevent a patent owner from enforcing a patent where the alleged acts of infringement constitute certain research or other experimental uses of an invention claimed in the patent. The exception in § 271(j) contains four separate categories of such uses. Each of these categories is set out in terms that are broad enough to assure that patents cannot block access to the basic tools of scientific and technological work. Taken together, the scope of the exception assures that patents cannot operate to frustrate their constitutional purpose to promote, rather than impede, progress in the useful arts.

This new infringement exemption is based in part on a recommendation for addressing this issue that was developed by the National Academies of Science in its report *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (http://www.nap.edu/catalog/11487.html)[6] and was supported by the National

[6] At p. 145 of the report the following recommendation (Recommendation 10) appears:
"Congress should consider exempting research "on" inventions from patent infringement liability. The exemption should state that making or using a patented invention should not be considered infringement if done to discern or to discover:
"a. the validity of the patent and scope of afforded protection;
"b. the features, properties, or inherent characteristics or advantages of the invention;
"c. novel methods of making or using the patented invention; or
"d. novel alternatives, improvements, or substitutes."

Academies in part because it would align U.S. patent law with that of other industrialized countries.

In general, therefore, the new § 271(j) would create an infringement exception that encompasses any philosophical or scientific inquiries where the object is gaining knowledge regarding the patented invention. As suggested in the National Academies' recommendation, exemplary activities of this type include efforts to discover, identify or discern the (1) validity of the patent or the scope of protection afforded under the patent; (2) any features, properties, inherent characteristics, or advantages of the patented subject matter; (3) methods of making or using the patented subject matter; and, (4) alternatives to the patented subject matter. The latter can encompass any type of improvement or other alternative to the patented subject matter.

These exclusions are premised on the understanding that the public must be able to develop a complete understanding of the patented subject matter and be able to use that understanding to advance the useful arts, *e.g.*, by using the patent's disclosure as a starting point for making further discoveries. Without this freedom, a patent grant could be used to stop further progress in the useful arts during the term of protection afforded under the patent, inconsistent with the constitutional purpose of the patent system.

As such, § 271(j) provides assurance that progress in the useful arts through the discovery of new technology could never be impeded by patent rights chocking off access to the tools on which experimentation was needed to improve them or invent other alternatives to them.

(2) POST ISSUANCE REVIEW REFORMS:

> *Strike chapter 32 and the entries in the table of sections relating thereto and, in chapters 10 and 31:*
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> *(A) PERMITTED SCOPE FOR REVIEW AND PRIOR ART.—*
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> *(1) SCOPE OF PROCEEDING.—In section 311(b), strike "only on a ground" and insert "on any ground that could be raised under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim), except that a petition filed more than 9 months after the issue date of the patent may only raise a ground of invalidity under section 102 or 103 based upon patents and printed publications that constitute prior art."*

(2) PRIOR ART CLARIFICATION.—In section 102(a)(1), strike "or in public use, on sale," and in section 282 of title 35, United States Code, insert at the end—

"(d) UNENFORCEABILITY DEFENSE.—If the inventor or a joint inventor of a claimed invention in a patent, or another who obtained the subject matter claimed directly or indirectly from the inventor or a joint inventor, had placed the claimed invention in public use or on sale in the United States more than six years prior to the effective filing date of the claimed invention, the patent shall be unenforceable unless, prior to the date on which the patent was originally issued, the patentee had disclaimed under section 154(b) the term of the patent extending beyond 21 years from the date on which the claimed invention was ready for patenting by the inventor."

(B) In section 311(b), strike the text after the word "shall" and insert "not be filed before 3 months after the grant of a patent.".

(C) In section 314(a), insert at the end, "Notwithstanding the preceding sentence and absent of showing of exceptional circumstances, the Director may not authorize an inter partes review of a patent in which a determination was made prior to the date of the petition for review not to institute an inter partes review a pursuant to the filing of another petition for review under this chapter.

(D) In section 314, insert at the end:

"(e) SCOPE OF REVIEW, PRIOR-ADJUDICATED CLAIMS EXCLUDED.—If instituted, an inter partes review shall address each of the grounds of invalidity raised in the petition with respect to each of the challenged claims for which, prior to the final written decision in the review under section 318(a), the validity of the claim has not been adjudicated (1) in a final written decision in another review under this chapter or (2) in an appealable or nonappealable final judgment entered in a civil action or in a proceeding at the International Trade Commission."

(E) In section 316(c), strike the text after "by" and insert "clear and convincing evidence, interpreting the claims as they would be construed in a civil action under section 271.".

The post-issuance review procedures in the United States Patent and Trademark Office could be amended in multiple respects with the objective of providing a relatively prompt and relatively inexpensive alternative to assuring that patents with invalid claims could be administratively canceled with the time and expense needed for an adjudication in a district court infringement action. The specific changes that would take effect based on the amendments proposed above are the following:

A. Post-Grant Review Superseded

The provisions under chapter 32 of title 35, United States Code, are repealed. The expansion of the availability of inter partes review procedures under chapter 31 of title 35 eliminates any need for maintaining essentially duplicative provision in chapter 32 authorizing post-grant reviews of issued patents.

B. Permitted Scope for Review and Prior Art

35 U.S.C. § 311(b)[7] is amended to authorize an inter partes review on any ground that could be raised under as an invalidity defense in a patent infringement action so long as the petition for the inter partes review is filed within 9 months after the issue date of the patent.[8] This includes any issues of patentability arising under 35 U.S.C. § 101, § 102, § 103,and § 112. A petition that is filed after the 9-month period ends may only raise a ground of invalidity under section 102 or 103 based upon patents and printed publications that constitute prior art."[9]

This new jurisdiction for an inter partes review extends to all patents, including those that would be eligible under the transition provision for covered business method patents under § 18 of the America Invents Act. For patents not subject to the first-inventor-to-file provisions of the America Invents Act, the new jurisdiction for inter partes review proceedings extends to patents and published patent

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[7] 35 U.S.C. § 311(b) currently reads:

"(b) SCOPE.—A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications."

[8] Post-grant review procedures have a scope that is set out in 35 U.S.C. § 321(b):

"(b) SCOPE.—A petitioner in a post-grant review may request to cancel as unpatentable 1 or more claims of a patent on any ground that could be raised under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim)."

[9] Under the effect and effective date provisions, the "patents and printed publications" limitation would be made additionally applicable to all first-to-invent patents, *i.e.*, patents that were not subject under the America Invents Act to the "post-grant review" procedure under which all issues of patentability could be considered by the United States Patent and Trademark Office.

applications that constitute prior art under pre-AIA 35 U.S.C. § 102(e),[10] which is a ground that is not available for review under the transitional provision for covered business method patents.[11]

The amendment clarifies the standard for determining prior art under 35 U.S.C. § 102(a)(1) of the America Invents Act. It overrules a recent Supreme Court decision[12] that had negated the implementation of § 102(a)(1) by the United States Patent and Trademark Office (through its guidance to inventors and practitioners[13]) and disregarded what one of the principal congressional architects and sponsors of the Act has indicated was the intent of Congress in enacting § 102(a)(1).[14]

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[10] Under § 18(a)(1)(C) of the American Invents Act, prior art is limited to subject matter that has been made available to the public under pre-AIA 35 U.S.C. § 102(a) and § 102(b), but excludes prior art arising from patent filings or prior inventions before the date of invention of the claimed invention in an application for patent:

"A petitioner in a transitional proceeding who challenges the validity of 1 or more claims in a covered business method patent on a ground raised under [pre-AIA] section 102 or 103 of title 35, United States Code, … may support such ground only on the basis of—

"(i) prior art that is described by [pre-AIA] section 102(a) of such title …; or

"(ii) prior art that—

"(I) discloses the invention more than 1 year before the date of the application for patent in the United States; and

"(II) would be described by [pre-AIA] section 102(a) of such title … if the disclosure had been made by another before the invention thereof by the applicant for patent."

[11] The provisions of § 18 of the America Invents Act expire at the end of the 8-year period after the covered business method patent proceedings became effective on September 20, 2012. The expansion of the jurisdiction of inter partes review proceedings obviates any need for Congress to extend the transition period.

[12] *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc.*, 139 S. Ct. 628 (2019)

[13] "The starting point for construction of a statute is the language of the statute itself. A patent is precluded under AIA 35 U.S.C. 102(a)(1) if 'the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.' AIA 35 U.S.C. 102(a)(1) contains the additional residual clause 'or otherwise available to the public.' Residual clauses such as 'or otherwise' or 'or other' are generally viewed as modifying the preceding phrase or phrases. Therefore, the Office views the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that *secret sale or use activity does not qualify as prior art*." [Emphasis added.] *Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the America Invents Act*, https://www.uspto.gov/web/offices/com/sol/og/2016/week52/TOCCN/item-230.htm.

[14] "Congress altered the patent law dramatically with the American Invents Act… . The changes were based on a set of recommendations from the National Research Council of the National Academies. At the urging of the NRC, Congress abandoned the first-to-invent principle, a bedrock of patent statutes for 175 years. Congress did so in large measure because that principle had complicated the law on 'prior art' and fostered the creation of numerous 'loss of right to patent' provisions. Moreover, such features of U.S. patent law placed the United States out of step with every other country in the world.

"Congress based its new patent statute on the first-inventor-to-file principle in order to fashion a simplified and internationalized set of conditions for patentability in new §§ 102-103. This

The text of 35 U.S.C. § 102(a)(1)[15] enacted under the America Invents Act is amended to remove the words "in public use" and "on sale" from the statute as a means to limit prior art to subject matter that is available to the public. The standard "available to the public" is identical to the standard for qualifying subject matter as prior art , *i.e.*, as "known or used,"[16] under pre-AIA 35 U.S.C. § 102(a).[17] By removing the terms "in public use" and "on sale," the amended text limits prior art to subject matter to that which has been "patented, described in a printed

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allowed Congress to enact a new § 102 limited to a requirement for novelty. It further allowed a dramatic clarifying and streamlining of the definition for prior art.

"The changes to the law arising from the drafting of new § 102's "prior art" provision involved retiring the phrase "known or used" from repealed § 102(a)'s definition of prior art, notwithstanding that this phrase had been used to define "prior art" in every patent statute since 1790. It was replaced with an alter ego term, 'available to the public.'

"This new terminology is used internationally to define prior art, in part by excluding confidential or otherwise secret subject matter from qualifying as prior art. It is also used judicially in the United States to explain that subject matter could qualify under repealed § 102(a) as 'known or used' only when publicly disclosed. Most significantly, the term 'available to the public' in new § 102(a)(1) now functions as a terminal qualifier limiting prior art arising from 'in public use' or "on sale" activities to what renders the subject matter defined by the patent claims available to the public.

"Thus, to the end of a simpler and more internationalized patent system, the new statute both eliminated 'loss of right to patent' provisions in which inventor-attributable activities might bar a patent under old § 102 irrespective of whether the subject matter defined by the claims was made publicly available and similarly limited the 'novelty' bar to patenting such that the subject matter defined by a claim must now be available to the public. The simplicity of the new statute makes it difficult to read in any other way.

"Even if it could be so read, there would be no justification as a matter of patent policy to do so. Congress determined that preserving patentability so long as the subject matter of a patent claim had not been publicly disclosed would provide a continuing incentive to disclose novel and non-obvious subject matter. In contrast, the repealed law operated to encourage continued secrecy once the right to patent had been forfeited though 'on sale' activities attributable to the inventor, even if secret. The America Invents Act aligns with the patent system's constitutional purpose to encourage disclosure and, thus, promote progress in useful arts by replacing that incentive for secrecy with a continuing incentive to disclose." *Helsinn v. Teva*, Amicus Brief of Congressman Lamar Smith, pp. 2-3, https://www.supremecourt.gov/DocketPDF/17/17-1229/60461/20180823130453156_17-1229%20Amicus%20Brief%20of%20Congressman%20Lamar%20Smith.pdf.

[15] 35 U.S.C. § 102(a)(1) under the America Invents Act provides that a claimed invention lacks "novelty" over prior art if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention … ."

[16] "[Pre-AIA]Section 102(a) establishes that a person cannot patent what was already known to others. … Accordingly, in order to invalidate a patent based on prior knowledge or use, that knowledge or use must have been available to the public." *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).

[17] Pre-AIA § 102(a) provided that "A person shall be entitled to a patent unless … the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent… ."

publication, or otherwise available to the public before the effective filing date of the claimed invention … ."

This amendment is necessary not only to conform prior art determinations under the America Invents Act to the legislative intent of Congress in enacting the Act, *but specifically to assure the administrability of the post-issuance review procedures in which all forms of prior art may be raised for adjudication, i.e., assure that the statutory time constraint (one-year deadline from institution to reach a final written decision on all grounds of patentability) can be met while affording such discovery as would be needed for fairness.*[18]

The amendment adopts the view of the lead sponsor of H.R. 1249 (112th Congress), the bill that became the America Invents Act, that all prior art under the America Invents Act should be limited to subject matter available to the public in part based upon the need to limit the nature and extent of discovery that might be necessary to fairly adjudicate patentability in post-issuance review proceedings.[19] The return of the "prior art" law to the manner in which the United States Patent and Trademark Office implemented the new statute (and Congress conceived and enacted it) is consistent with sound patent policy under the first-inventor-to-file provisions of the America Invents Act[20] and will secure the ability of the United States Patent and

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[18] The inter partes review statute requires "that the final determination in any post-grant review be issued not later than 1 year after the date on which the Director notices the institution of a proceeding under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months… ." 35 U.S.C. § 316(a)(11).The post-grant review statute contains a substantively identical provision in 35 U.S.C. § 326(a)(11).

[19] See p. 18 of *Helsinn v. Teva*, Amicus Brief of Congressman Lamar Smith noting that the extension of "in public use" and "on sale" prior art to secret, non-public, as well as foreign, activities will "invite discovery of the activities of inventors and their assignees to determine if the patent right has been forfeited. Such provisions in the patent law can greatly compromise the efficiency and effectiveness of yet another seminal change to the U.S. patent law, the new post-grant review procedures enacted as part of the America Invents Act. Congress provided the opportunity for any member of the public to challenge the validity of any newly issued U.S. patent on any ground that could be raised as a defense to the infringement of the patent, but in a proceeding designed with a one-year time limit for reaching a final decision—*a limit premised on Congress's determination that discovery burdens in the old law would be gone in the new*." [Emphasis in original.]

[20] See pp. 31-32 of *Helsinn v. Teva* Amicus Brief of Congressman Lamar Smith : "[T]he manner in which such a bar has been implemented by the courts has always had elements that were more punitive than principled. For example, … the "on sale" bar [has been] applied to an invention before it had ever been actually made—when it was merely 'ready for patenting'—and applied when the commercialization activities were otherwise inconsequential, *i.e.*, one-off sales that were at most *de minimis*. The result of such an oversized bar has been to impose a burden on the inventor to seek a patent unjustifiably early, if for no other reason than the standard for 'readiness' can be so subjective and threshold for triggering the bar can be so low.

"For an invention never actually made in physical form nor yet available for purchase—or sold only in trifling quantities or 'on sale' only for a matter of days beyond an arbitrary deadline—there is not now nor has there ever been any compelling patent policy that should demand absolute

Trademark Office to conduct the post-issuance review proceedings when prior art is asserted that is not based upon a printed publication or a published patent document.

The amendment substitutes a defense of unenforceability under a new 35 U.S.C. § 282(d) for a patent if the patent contains a claimed invention that was "in public use or on sale" more than six years prior to the effective filing date of the claimed invention. This provision effectively creates a *patent filing laches* ground for preventing a patent from being enforced where such "in public" use" or "on sale" activities are attributable to the inventor (or a joint inventor).[21] If the patent owner—prior to the issuance of the patent—files a terminal disclaimer of any term of the patent that would extend for more than 21 years from the date the invention was ready for patenting,[22] the patent filing delay is excused, and the patent can be enforceable.

The new § 282(d) unenforceability defense operates by mandating that all of the law and legal principles that have been recognized as a *statutory bar to patenting* be continued,[23] but, under § 282(d), in the form of a bar to enforceability. Where

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forfeiture of the right to patent. Whatever rule might be justified in the case of substantial, longstanding, and ongoing 'on sale' activities (*i.e.*, sales in which profits from commercially significant quantities sold have been realized, with such sales taking place over a period of many years before seeking a patent), it is hard to articulate a similar justification for barring a patent… ."

[21] This continues, as an unenforceability doctrine, the invalidity (abandonment) doctrine described by the Supreme Court in *Pfaff v. Wells Electronics, Inc.*, 525 US 55, 64 (1998), including its "experimental use" exception:

"We originally held that an inventor loses his right to a patent if he puts his invention into public use before filing a patent application. 'His voluntary act or acquiescence in the public sale and use is an abandonment of his right.' *Pennock v. Dialogue*, 2 Pet. 1, 24 (1829) (Story, J.). A similar reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar.

"Nevertheless, an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention—even if such testing occurs in the public eye. The law has long recognized the distinction between inventions put to experimental use and products sold commercially."

[22] See *Pfaff* at 525 US 67-68 (1998):"[T]he invention must be ready for patenting [for a bar to apply]. That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention."

[23] The preservation of all pre-AIA "in public use" and "on sale" activities as the basis for preventing patent rights from being enforced through new § 282(d) moots the concerns raised in *Helsinn v. Teva* that restricting prior art to publicly available activities would discard longstanding precedents without sufficient justification. "[I]t [by restricting 'in public use' and 'on sale' activities to those 'available to the public'] would sweep away scores of cases, accumulated over two centuries, defining in great detail each of the specific categories of prior art listed in AIA § 102(a). Opinions by giants in the patent field, from Joseph Story to Learned Hand to Giles Rich – gone, by virtue of one added word in the new statute." *Helsinn v. Teva*, Amicus Brief of 45 Intellectual Property Law

longstanding, inventor-attributable "in public use" or "on sale" activities have taken place, an inventor can secure enforceable patent rights only if the exclusionary rights under the patent are limited in time to no longer than the patentee could have secured had the inventor sought a patent within one year from the initiation of the "in public use" or "on sale" activities.

C. Time Limitation for Petition for Inter Partes Review

An amendment to 35 U.S.C. § 311(c)[24] permits an inter partes review petition to be filed at any time after 3 months from the issue date of a patent. The provision will facilitate joinder of petitioners in situations where multiple petitioners desire to seek an inter partes review immediately upon issuance of a U.S. patent.

D. Limitations in Case of Prior a Prior Determination

One of two amendments are made to 35 U.S.C. § 314[25] that reduce the burdens on the patent owner that the inter partes review procedure might otherwise impose. The first of these amendments requires that a petitioner demonstrate exceptional circumstances in order for an inter partes review petition to be granted on a patent in which a determination was made not to institute an inter partes review pursuant

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Professors, p. 11, http://www.supremecourt.gov/DocketPDF/17/17-1229/66149/20181009122047518_17-1229_Helsinn%20v.%20Teva_bsac.pdf. The entire body of precedent would remain in place as a statutory *patent filing laches* unenforceability bar.

[24] 35 U.S.C. § 311(c) under the America Invents Act reads:

"(c) FILING DEADLINE.—A petition for inter partes review shall be filed after the later of either—

"(1) the date that is 9 months after the grant of a patent; or

"(2) if a post-grant review is instituted under chapter 32, the date of the termination of such post-grant review."

[25] 35 U.S.C. § 314 reads:

"**§ 314 Institution of inter partes review.**

"(a) THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

"(b) TIMING.—The Director shall determine whether to institute an inter partes review under this chapter pursuant to a petition filed under section 311 within 3 months after—

"(1) receiving a preliminary response to the petition under section 313; or

"(2) if no such preliminary response is filed, the last date on which such response may be filed.

"(c) NOTICE.—The Director shall notify the petitioner and patent owner, in writing, of the Director's determination under subsection (a), and shall make such notice available to the public as soon as is practicable. Such notice shall include the date on which the review shall commence.

"(d) NO APPEAL.—The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.

to a prior petition. An additional sentence is added to § 314(a) to introduce this limitation into the patent statute.

The primary effect of this provision will be to prevent serial petitions from being filed by the same petitioner. In such circumstances the required showing of exceptional circumstances presents a formidable hurdler for the serial petitioner. For other petitioners, the requirement for a showing of exceptional circumstances would constitute a significant, but not insuperable, hurdle.

E. Limitation in Case of a Prior Adjudication

A second change to § 314 is made to add a new subsection (e) to the end of this section. This new subsection prevents the United States Patent and Trademark Office from undertaking an inter partes review of a claim that has been the subject of a final written determination in a prior inter partes review proceeding or has been adjudicated not to be invalid in a prior civil litigation or International Trade Commission proceeding. This provision applies irrespective of whether the earlier adjudication was or was not appealed and does nor does not remain appealable.

F. Standards for Review

An amendment is made the 35 U.S.C. § 316(c)[26] imposing the same "clear and convincing evidence" standard applied to factual questions[27] and the same claim construction standard[28] that are used in civil actions when invalidity is raised as a defense to infringement. These amendments assure that the adjudication of the validity of a claim in an inter partes review procedure will proceed under the identical legal standards that would be applicable if the claim were adjudicated in other forums.

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[26] 35 U.S.C. § 316(c) reads: "(e) EVIDENTIARY STANDARDS.—In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence."

[27] See *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238, 2253 (2011) (J. Breyer, concurring):

"[T]his area of law as in others the evidentiary standard of proof applies to questions of fact and not to questions of law. … Thus a factfinder must use the 'clear and convincing' standard where there are disputes about, say, when a product was first sold or whether a prior art reference had been published.

"Many claims of invalidity rest, however, not upon factual disputes, but upon how the law applies to facts as given. …. Do they show that the patent applicant described his claims properly? [35 U.S.C.]§ 112. Where the ultimate question of patent validity turns on the correct answer to legal questions—what these subsidiary legal standards mean or how they apply to the facts as given—today's strict standard of proof has no application."

[28] In a civil action, claims are to be given their 'ordinary meaning ... as understood by a person of skill in the art." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314.

(3) FINDINGS, RULES OF CONSTRUCTION, AND MISCELLANEOUS AMENDMENTS

(b) FINDINGS, RULES OF CONSTRUCTION, AND MISCELLANEOUS AMENDMENTS.—

(1) ABROGATION OF IMPLICIT EXCEPTIONS.—The implicit exception to subject matter that is eligible for patenting under section 101 of title 35, United States Code, for claimed inventions deemed to be directed to a natural law or phenomenon or abstract idea or like subject matter is hereby abrogated, as creating uncertainties and consequences that Congress finds to be inconsistent with the constitutional purpose of the patent system to promote progress in useful arts. Section 101 must be applied as though it contains no implicit exception to the subject matter that can qualify under section 101 as eligible for patenting and the eligibility of a claimed invention for patenting cannot be negated by the manner in which the invention was made or by considering whether individual elements of the claim can be regarded as being inventive.

(2) CLAIM LIMITATIONS.—For the purposes of determining if a claimed invention is patentable, or has been infringed, each element or other applicable limitation of the claim must be identified and the subject matter being claimed must be considered as a whole, based on such limitations as so construed and without disregard for any limitation the claim is construed to contain, except that, notwithstanding any other provision of this Section, nothing in this Section or section 101 of title 35, United States Code, may be construed to permit a claim in a patent to be found eligible for patenting under section 101 if the claim is directed to—

(A) a law, phenomenon, idea, or other concept as such,

(B) a product as it exists in nature (including any gene or other genetic material, such as a human gene or human genetic material),

(C) a claimed invention that is computer-implemented in which—

(i) the computer-implemented claim limitations are sufficiently general in character that the claim could be infringed by making or using the claimed subject matter on a general-purpose computing device and

(ii) absent such computer-implemented claim limitations, the claimed invention would be ineligible for patenting under section 101.

(3) NON-STATUTORY GROUNDS FOR REFUSAL TO GRANT A PATENT UNAFFECTED.—Notwithstanding any other provision of this Section, the Director of the United States Patent and Trademark Office may refuse to grant a patent on an application on the grounds of (a) prosecution laches, (b) other prosecution misconduct, (3) non-statutory double patenting, or (4) deemed abandonment of the application, if such refusal to grant a patent on such application would have been permitted by law had this Section not been enacted into law.

(4) DISCLOSURE SUFFICIENCY UNDER SECTION 112(a) A QUESTION OF LAW.—

(A) FINDINGS.—Notwithstanding any other provision under this Section, Congress finds that—

(i) the decisions of the Supreme Court in O'Reilly v. Morse, 56 U.S. 62 (1854) and Halliburton Oil Well Cementing Co. v. Walker, 329 U.S. 1 (1946) must remain controlling interpretations of the standard for a sufficient disclosure under section 112(a) of title 35, United States Code, and

(ii) the requirement for a sufficient written description under section 112(a) includes, as a consequence, a requirement that the disclosure in the specification of a patent or an application for patent, as the case may be, be sufficient to establish the inventor had completed the conception of any invention being claimed, which conception has been properly determined by the courts to be a question of law.

(B) INTERPRETATION.—The requirement under section 112(a) for a sufficient disclosure must be interpreted as addressing a question of law with respect to whether the written description in the specification of a patent or an application for patent, as the case may be, is sufficient to demonstrate that a completed conception of a claimed invention existed, in addition to the separate question of law with respect to whether the specification provides an enabling disclosure thereof, including a practical utility.

> *(C) APPLICATION DISCLOSURE CLARIFICATION.—In section 112(a) of title 35, United States Code, strike all that follows after "same"; in section 282 of United States Code, strike ", except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable"; and in section 119(e)(1) of United States Code, strike "(other than the requirement to disclose the best mode)"*
>
> *(5) APPLICABILITY PRESUMPTION FOR FUNCTIONAL CLAIM ELEMENTS.—The applicability or inapplicability of the limitations on the subject matter covered by an element in a claim to a combination under subsection (f) of section 112, United States Code, must be determined in accordance with the canons of claim construction, without any presumption as to such applicability or inapplicability based on whether or not any particular words or phrases are used in the claim element, including words such as "means for" or "step for" or the like.*

As the Subcommittee works to clarify the proposed reforms to § 101, the following set of five findings and rules of construction are offered as additional items to be enacted into law. These five paragraphs would address:

(1) the abrogation of implicit exceptions to the subject matter that is eligible for patenting together with a prohibition on considering for eligibility purposes the manner in which the invention was made or whether individual elements of a claim are inventive in determining eligibility for patenting;

(2) the necessity for all claim limitations to be considered in the determination of patentability and patent infringement, while recognizing that patent eligibility extends neither to concepts as such nor to otherwise patent ineligible subject matter that is merely computer-implemented;

(3) the preservation of the non-statutory grounds for refusing to grant a patent based on prosecution laches, other prosecution misconduct, obviousness-type double patenting, and failure to properly respond to the United States Patent and Trademark Office (deemed abandonment);

(4) the preservation of the Supreme Court precedents on disclosure sufficiency (35 U.S.C. § 112(a)), including the further recognition that disclosure sufficiency is a question of law (not a question of fact), and thus not subject to a clear and convincing evidentiary standard in establishing the invalidity of a claim; and

(5) a bar to the use of presumptions in the determination of the applicability or inapplicability of 35 U.S.C. § 112(f) to a claim element.

(a) Abrogation of Implicit Exceptions

Under paragraph (1), any implicit exception to the subject matter expressly defined in amended § 101 as being eligible for patenting is abrogated. Amended § 101 must be applied as though no implicit exception to subject matter eligible for patenting is present in amended § 101. This construction of the statute expresses the finding of Congress that the implicit exception imposed by the courts has created uncertainties and other adverse consequences that Congress finds to be inconsistent with the constitutional purpose of the patent system to promote progress in useful arts, necessitating congressional abrogation.

In addition, any consideration of the manner in which the invention was made or the inventiveness of any claim element in the determination of subject matter eligibility under § 101 is eliminated. Issues relating to inventiveness of claim elements are addressed in the statutory non-obviousness requirement under 35 U.S.C. § 103 by imposing a requirement for inventiveness with respect to the subject matter as a whole being claimed, thereby obviating the need for a second, inventiveness-related standard for determining if a patent claim is valid or a patent may be granted on a claim.

(b) Claim Limitations

Under paragraph (2), an "all elements" rule of claim construction[29] is set forth that applies broadly to issues of patentability and patent validity as well as issues of patent infringement. This rule restates a longstanding requirement that each element or other limitation in a claim must be considered in the assessment of the protection afforded under a claim in a patent or an application for patent, irrespective of the purpose for which the assessment is being made. This rule of construction prevents a court, in applying a statutory condition or requirement for patentability (or an aspect of judge-made law on patenting), to find a patent claim ineligible for patenting—or insufficiently disclosed—by disregarding any element or other claim limitation that might confine the scope of protection afforded under the

[29] "Claims in patents are typically drafted in the form of a preamble, transition and one or more elements. Each element constitutes a limitation or narrowing of the scope of the claim. It follows that a claim will not cover or 'read on' any device or process unless that device or process contains all the elements of the claim (or an equivalent thereof within the meaning of the doctrine of equivalents). This rule is frequently applied by the courts to so-called 'combination' claims. However, the rule in fact is a universal one of claim drafting and construction." Pennwalt Corp. v. Durand-Wayland, Inc., 833 F. 2d 931, 949 (Fed. Cir. 1987), quoting D. Chisum, *Patents* (v. 4) § 18.03[4] (1986):

claim to patentable subject matter. Thus, this rule of construction is specifically applicable to the determination of subject matter eligibility for patenting.

In addition, this paragraph contains a carve-out under which nothing in the law is to be construed as permitting a claim to a law, phenomenon, idea, or other concept as such or to a product as it exists in nature (including any gene or other genetic material, such as a human gene or human genetic material) to be found patent eligible under § 101. This paragraph would require that § 101 be construed to preserve the holding in *Ass'n for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013), invalidating as ineligible for patenting claims directed to human genomic DNA sequences for the human BRCA gene, to the extent claims could be construed to secure protection for the human gene as it exists in nature. It would further preserve the additional holding in *Myriad* that the "copy DNA" or "complementary DNA" (cDNA) relating to a human gene can be eligible for patenting to the extent such claims cannot be construed to secure protection for the human gene as it exists in nature and, most specifically, preserve the holding that the Myriad claims to the cDNA for a human BRCA gene would be regarded as eligible for patenting under § 101.[30]

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[30] As a more specific and direct alternative (or as an addition to the paragraph above) relating to the patenting of naturally occurring subject matter, the Subcommittee might consider the following rule of construction:

"GENOMIC DNA COMPOUNDS INELIGIBLE FOR PATENTING; SUBJECT MATTER OTHERWISE ELIGIBLE.—Nothing in this Section shall be construed to overrule the holding of the Supreme Court in Ass'n for Molecular Pathology v. Myriad, 133 S. Ct. 2107 (2013), including the holding that a claimed invention comprising the isolated DNA discovered in a subpart of a chromosome shall be ineligible for patenting. Section 101(b) of title 35, United States Code, must be construed to mean that a claim comprising any isolated DNA compound formed from a sequence of nucleotide base pairs discovered in a subpart of an intact chromosome, as such, shall not be regarded as a practically useful application of technology to an area of human endeavor. This Section must further be construed to overrule the holding of the Supreme Court in Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) to the extent such holding could be construed to mean that the claimed inventions addressed in this decision would represent subject matter ineligible for patenting. Nothing in the preceding sentence may be interpreted to mean that the claimed inventions in Funk Brothers Seed Co. must be regarded as patentable under the requirements for non-obviousness under section 103 of title 35 or sufficiency of disclosure under section 112 of title 35, United States Code."

This rule of construction could include a commentary, such as the following:

The Supreme Court in *Ass'n for Molecular Pathology v. Myriad*, 133 S. Ct. 2107, 2117, 2118 (2013) held that genomic DNA, *i.e.*, DNA that was discovered in a subpart of a human chromosome was ineligible for patenting: "Myriad explains that the location of the gene was unknown until Myriad found it among the approximately eight million nucleotide pairs contained in a subpart of chromosome… . Myriad's patent descriptions simply detail the 'iterative process' of discovery by which Myriad narrowed the possible locations for the gene sequences that it sought. … Myriad's claims [are not] saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from

It would also prescribe, as a further rule of construction, that nothing in the law is to be construed as permitting a claim to a computer-implemented invention to be found patent eligible under § 101 if the claim would otherwise be found ineligible for patenting under § 101 but for claim limitations of a sufficiently general in character that the claim could be infringed by making or using the claimed subject matter on a general-purpose computing device. This rule of construction would preclude the patenting of patent ineligible subject matter that contained only the additional claim limitation "on a computer."[31]

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the isolation of a particular section of DNA." This holding of the Supreme Court is preserved with respect to claims to DNA compounds that seek to protect a subpart of a chromosome as such, *e.g.*, the genomic DNA for a human gene. Also preserved is the holding of the Supreme Court in *Myriad* that complementary DNA (copy DNA) is eligible for patenting, *e.g.*, the cDNA of the human BRCA genes. "[W]e hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring." 133 S.Ct. 2111. In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) the Supreme Court held unpatentable a claim to an "inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus Rhizobium, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific." The concurring opinion of the Court would have found the claim unpatentable for lack of a sufficient disclosure, "[T]wo different claims of originality are involved: (1) the idea that there are compatible strains, and (2) the experimental demonstration that there were in fact some compatible strains. Insofar as the court below concluded that the packaging of a particular mixture of compatible strains is an invention and as such patentable, I agree, provided not only that a new and useful property results from their combination, but also that the particular strains are identifiable and adequately identified. I do not find that Bond's combination of strains satisfies these requirements. The strains by which Bond secured compatibility are not identified and are identifiable only by their compatibility." The analysis of the claimed invention in *Funk Brothers Seed Co.* in the concurring opinion is not affected by the rule of construction of section 101 of title 35, United States Code, that would preclude the majority opinion of the Court from being interpreted to require a finding that the subject matter claimed was ineligible for patenting, *i.e.*, was not a "manufacture" or "composition of matter" making "a specific and substantial contribution to a useful art through a practically useful application of technology to an area of human endeavor."

[31] A claim of the following form would be ineligible for patenting, based on the preservation of the outcome in the Supreme Court's disposition of the Bilski claims in *Kappos v. Bilski*:

"A ***computerized*** method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:

"(a) initiating ***on a computer*** a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;

"(b) identifying ***on a computer the*** market participants for said commodity having a counter-risk position to said consumers; and

"(c) initiating ***on a computer*** a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions."

(c) Non-Statutory Grounds to Refuse to Grant a Patent Unaffected

Under paragraph(3), a final rule of construction preserves the ability of the United States Patent and Trademark Office to refuse to grant a patent on an application on the basis of prosecution laches (*In re Bogese*, 303 F.3d 1362 (Fed. Cir. 2002)), prosecution misconduct otherwise ("inequitable conduct" in violation of 37 C.F.R. § 1.56; *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276 (Fed. Cir. 2011)), obviousness-type double patenting (*Sun Pharmaceutical Industries, Ltd. v. Eli Lilly and Co.*, 611 F.3d 1381 (Fed. Cir. 2010)), or a deemed abandonment of the application by virtue of failure to respond to the Office (failure to respond to a request for information under 37 C.F.R. § 1.105; *Star Fruits SNC v. US*, 393 F.3d 1277 (Fed. Cir. 2005)). Together with the conditions and requirements for patentability under Title 35, these would be the sole additional grounds on which the United States Patent and Trademark Office might refuse to grant a patent to a person otherwise entitled to a patent for a claimed invention under 35 U.S.C. § 101.

(d) Disclosure Sufficiency under Section 112(a) a Question of Law

Under paragraph (4), Congress makes express findings that the decisions of the Supreme Court on the question of sufficiency of the disclosure in the specification of a patent or an application for patent are preserved and remain controlling law. In addition, Congress makes an express finding that the question of sufficiency of disclosure is a question of law, *i.e.*, both the § 112(a) "written description" and § 112(a) "enablement" requirement represent questions of law. With the amendment to § 112(a) removing the reference to the "best mode" disclosure requirement, these requirements for "written description" and "enablement" are the sole requirements for a sufficient disclosure present under § 112(a).[32]

In this regard, the courts have held that whether the inventor has conceived an invention, which is a predicate to being able to communicate a written description of a claimed invention, is a question of law. "Priority, conception, and reduction to practice are questions of law which are based on subsidiary factual findings." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327(Fed. Cir. 1998). "This court reviews a

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The above claim recites computer-implemented claim limitations that are sufficiently general in character that the claim could be infringed by making or using the claimed subject matter on a general-purpose computing device and, absent such limitations, would be patent ineligible under § 101(b), as discussed herein above.

[32] The amendments remove a vestigial provision (the so-called "best mode" requirement) from the disclosure requirements for a patent specification. Following enactment of the America Invents Act, this "best mode" disclosure provision no longer has any bearing on whether a patent is valid and enforceable. Given the rule of construction proposed herein, these amendments result in the question of disclosure sufficiency under 35 U.S.C. § 112(a) being entirely a question of law.

determination of prior conception, which must be proven by facts supported by clear and convincing evidence, as a question of law based on underlying factual findings." *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573 (Fed. Cir. 1997). As such, the determination that an inventor possessed a conception of claimed invention through the written description in a patent specification, as required under 35 U.S.C. § 112(a), raises a question of law to be resolved based on any underlying facts that may need to be found.

The requirement that the patent specification enable the practice of a claimed invention is similarly a question of law. "Enablement is a question of law and is reviewed *de novo*." *In re Vaeck*, 947 F.2d 488, 495, (Fed. Cir. 1991)." "Whether disclosure is enabling is a question of law. *Raytheon Co. v. Roper Corp.* , 724 F.2d 951, 960 n.6 (Fed. Cir. 1983). The enablement requirement cannot be satisfied without making a subsidiary fact-finding that the claimed invention is in fact specifically and substantially useful, *i.e.*, meets the requirement under 35 U.S.C. § 101 for being practically useful. "The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention. (a foreign application does not satisfy section 112 if it fails to disclose a practical utility for the invention within section 101); … (if 'compositions are in fact useless, [applicant's] specification cannot have taught how to use them.'). If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112." *In re Ziegler*, 992 F2d 1197, 1200-1201 (Fed. Cir. 1993).

(e) Applicability Presumption for Functional Claim Elements

Paragraph (5) eliminates any presumptive applicability or inapplicability of 35 U.S.C. § 112(f) to a claim element based on the manner in which the functionally defined element is set out in the claim. In this regard, the decision in *Williamson v. Citrix Online, LLC,* 792 F. 3d 1339 (Fed. Cir. 2015), to the extent it addresses either the presumptive applicability or presumptive inapplicability of § 112(f) to the interpretation of a claim element, is overruled.

Under paragraph (5), § 112(f) will continue to be interpreted to require that a claim element be construed to determine if the description in the claim element defines a structure, material, or acts or, alternatively, if the description in the claim elements sets out a function to be performed. The function to be performed could be expressed as a result to be achieved, a property that would be exhibited, or a mechanism of action that would take place.

When the claim is interpreted as reciting such a function, then the claim element is limited for patent infringement purposes to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. However, under paragraph (5), in interpreting a claim element, the ordinary concepts of claim construction are applicable free from any presumption that § 112(f) is either applicable or inapplicable to a claim. Thus, the standards for claim construction in *Phillips v. AWH Corp.*, 415 F. 3d 1303 (Fed. Cir. 2005) must be used to determine whether § 112(f) applies to a claim element.

(4) SUBJECT MATTER ELIGIBILITY LIMITED TO PRACTICALLY USEFUL APPLICATIONS OF TECHNOLOGY TO AN AREA OF HUMAN ENDEAVOR

> *RIGHT TO PATENT ELIGIBLE SUBJECT MATTER; PRACTICALLY USEFUL APPLICATION REQUIRED.—In section 101, strike and insert:*
> ***"§ 101. Right to patent eligible subject matter; practically useful application required.***
> *"(a) RIGHT TO PATENT ELIGIBLE SUBJECT MATTER.—Whoever invents or discovers any process, machine, manufacture, or composition of matter, or any improvement thereof, shall be entitled to a patent therefor, absent a finding that one or more conditions and requirements of this title have not been met.*
> *"(b) PRACTICALLY USEFUL APPLICATION REQUIRED.—No claimed invention may be regarded as eligible for patenting under subsection (a) that does not make a specific and substantial contribution to a useful art through a practically useful application of technology to an area of human endeavor."*

The final set of changes to the draft bill relate to the amendment to § 101 itself and would incorporate a "useful arts" limitation expressed in term of a practically useful application of technology to an area of human endeavor. The following offers a commentary on this approach.

35 U.S.C. § 101 is repealed and replaced with a new section that consists of two new subsections. Subsection (a) provides that the inventor has the right to a patent a claimed invention meeting the conditions and requirements for patentability and further provides that only certain subject matter categories are eligible for patenting.

Subsection (b) imposes requirements that in part more fully codify judicial precedents that claimed inventions must specifically and substantially useful to be represent patent-eligible subject matter and in part imposes new requirements limiting patents to subject matter in which the required usefulness reside in a specific and substantial contribution to a "useful art" through a practically useful application of technology to a field of human endeavor. This latter requirement limits patenting to practically useful applications of technology that must fall within "useful arts" that Congress is constitutionally authorized to afford inventors exclusivity for their respective discoveries.

In § 101(a), four changes are made to the text of § 101 as enacted under the 1952 Patent Act. The text of amended § 101(a), as compared to the text of § 101 as enacted under the 1952 Patent Act:

(1) strikes the words "new and useful" at both occurrences;
(2) strikes the words "may obtain" and inserts the words "shall be entitled to";
(3) strikes the words "subject to the" and inserts the words "absent a finding that one or more"; and
(4) after the word "title" inserts the words "have not been met".

Compared to the text of § 101 enacted under the 1952 Patent Act, amended § 101(a) reads:

> (a) RIGHT TO PATENT; ELIGIBLE SUBJECT MATTER.—
> Whoever invents or discovers any ~~new and useful~~ process, machine, manufacture, or composition of matter, or any ~~new and useful~~ improvement thereof, ~~may obtain~~ shall be entitled to a patent therefor, ~~subject to the~~ absent a finding that one or more conditions and requirements of this title have not been met.

The change from "may be obtained" to "shall be entitled to" affords an inventor the right to patent a claimed invention in a patent application, provided the statutory conditions and requirements for patenting have been met. This subsection provides an unambiguous inventor's right to patent provision that replaces a provision to this same effect that formerly was present in 35 U.S.C. § 102 prior to the enactment of the America Inventions Act.

Specifically, the above text incorporates into § 101(a) the same statutory "right to patent" principle that was originally present in the preamble of 35 U.S.C. § 102, as enacted under the 1952 Patent Act. Under the 1952 Patent Act, § 102 provided that

an inventor has a right to a patent absent some finding that one or more of the conditions and requirements for patentability has not been met. This is best illustrated in the text of now-repealed § 102(f)[33] of the 1952 Patent Act that obligated the United States Patent and Trademark Office to allow a patent to be granted to an inventor on an inventor's claimed invention.[34] Since the enactment of the Leahy-Smith America Invents Act, there has been no comparable provision in the patent statute providing the inventor the same categorical right to patent formerly appearing in the pre-AIA § 102(f).[35] The above text of § 101 would remedy this drafting deficiency in the AIA.[36]

A second change in § 101(a) compared to § 101 under the 1952 Patent Act eliminates the words "new and useful" in two locations. These requirements for novelty and utility remain part of the law, but are detailed in other provisions in the statute.

The courts have held that the term "new" under § 101 represents a redundant reference to the "novelty" requirement under 35 U.S.C. § 102.[37] The removal of "new" from § 101, thus, eliminates any possibility that this term could be construed differently under § 101 from the established meaning it has under § 102.

The removal of this term from § 101 does not make any change in the so-called "doctrine of inherency" under which a claimed invention may be inherently anticipated by subject matter that exists in the prior art, even if not recognized or

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[33] Under § 102(f) enacted under the 1952 Patent Act, "A person shall be entitled to a patent unless … he did not himself invent the subject matter sought to be patented"

[34] *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984) and *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992), "If examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent. "

[35] Specifically, in rewriting § 102 as an entirely new provision of title 35, the AIA left the opening clause of subsection (a) of this section unchanged from the text of § 102 as enacted under the 1952 Patent Act. However, under the AIA, each of the loss of right to patent provisions were removed from § 102, including § 102(f). As a result, the current opening clause of § 102(a) has no readily apparent purpose and affords no predicate—including appropriate antecedents—for the substantive text that follows.

[36] The amended § 101 set out herein allows a conforming and correcting amendment to be made to § 102(a) that aligns its preamble with that of § 103, namely "A patent for a claimed invention may not be obtained if—". This more apt preamble for § 102(a) provides the necessary antecedent—now missing from § 102(a)'s chapeaux—for the term "claimed invention."

[37] *In re Bergstrom,* 427 F. 2d 1394, 1401 (CCPA 1970), "the criteria for determining whether given subject matter is 'new' within the meaning of § 101 are no different than the criteria for determining whether that subject matter possesses the 'novelty' expressed in the title of § 102. The word 'new' in § 101 is defined and is to be construed in accordance with the provisions of § 102. Thus, that which possesses statutory novelty under the provisions of § 102 is also new within the intendment of § 101. We have found no evidence of Congressional intent to define the word 'new' as used in § 101 in any different manner."

appreciated to so exist.[38] As a result, § 101(a) makes no change to longstanding precedents that prevent patents from being granted on any subject matter that already exists, including genes and other genetic material that exists in the human body and, therefore, cannot be patented under 35 U.S.C. § 102(a), irrespective of the subject matter eligibility requirement under § 101.

The additional requirement for a claimed invention to be useful to be eligible for patenting is set out in new 35 U.S.C. § 101(b). This subsection in part codifies existing law with respect to the required utility and in part sets forth an additional hurdle for subject matter to be eligible for patenting not previously codified in the statute.

New § 101(b) specifies that a claimed invention must have a specific and substantial usefulness in order to be eligible for patenting. Decisions of the courts have sometimes referred to this requirement as permitting only a *practically useful* invention to be patented. The "specific and substantial" or "practical" utility requirement set out in new § 101(b) codifies the court decision in *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005), a decision that relied heavily on the Supreme Court precedent in *Brenner v. Manson*, 383 U.S. 519 (1966). This existing requirement for usefulness is captured in the new text requiring "a specific and substantial contribution to a useful art."

The utility is required to be "through a practically useful application of technology to an area of human endeavor." The effect of this additional requirement is twofold. First, it requires finding that a claim has been limited to a "practically useful application." Second, that *application* must be of *technology* to an *area of human endeavor*."

As to the "areas of human endeavor" to which the application must be found, these are areas where natural laws, natural phenomena, and abstract ideas are applied, *i.e.*, are transformed into a practically useful process, machine, manufacture, or composition of matter. For the purposes of amended § 101, areas of human endeavor are those where humankind has intervened in the natural world to produce applications of laws, phenomena, or ideas exhibiting, which applications must exhibit some specific and substantial utility to be eligible for patenting.

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[38] The rule set out in *Peters v. Active Mfg. Co.*, 129 US 530, 537 (1889), where the Supreme Court adopted the principle that "That which infringes, if later, would anticipate, if earlier." The Federal Circuit has expanded on this rubric by explaining, "[t]hat which would literally infringe if later in time anticipates if earlier than the date of [the patent filing]." *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987).

In this regard, a claimed invention based on the discovery of a product existing in nature, such as genetic material functioning in the natural world (*e.g.*, a human gene) would not constitute subject matter eligible for patenting under § 101 except to the extent *applied* to an area of human endeavor (*e.g.*, diagnosis or treatment of disease), in which case a claimed invention based on an application of a law or phenomenon could be patented, but only if each of the additional patentability requirements of inherent novelty, non-obviousness, sufficiency of disclosure, and claim definiteness were also satisfied.

The requirement to be an "application of technology" affirmatively limits patentable subject matter to that contributing to the useful arts. This limitation gives explicit effect in the patent statute itself to the constitutional limitation on the power of Congress to enact laws affording inventors with exclusivity rights. Article I, Section 8, Clause 8, of the Constitution provides only that Congress shall have power "To promote the progress of … useful arts, by securing for limited times to … inventors the exclusive right to their respective … discoveries."

The "application of technology" limitation prevents a claimed invention from being eligible for patenting where the limitations found in the claims fail to confine the claims to a technological contribution to the useful art to which the invention relates. As a result, a claim to an improved method for playing a game such as the televised game *Jeopardy!*[39] would not be patent eligible subject matter under § 101(b), even if deemed highly inventive. Similarly, patents would be unavailable for methods lacking any technological steps, notwithstanding that the steps involved only physical activities.[40] The same limitation would apply to any non-technologically limited claim to a method of doing or conducting a business-related activity.[41]

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[39] See *How Jeopardy! Winner James Holzhauer Is Breaking Records*, TIME MAGAZINE (online), available at https://time.com/5589952/jeopardy-james-holzhauer-records/.

[40] See U.S. patent 6,368,227, claim 1: "A method of swinging on a swing, the method comprising the steps of: (a) suspending a seat for supporting a user between only two chains that are hung from a tree branch; (b) positioning a user on the seat so that the user is facing a direction perpendicular to the tree branch; (c) having the user pull alternately on one chain to induce movement of the user and the swing toward one side, and then on the other chain to induce movement of the user and the swing toward the other side; and (d) repeating step (c) to create side-to-side swinging motion, relative to the user, that is parallel to the tree branch."

[41] See claim 1 of U.S. Patent Application Serial No. 08/833,892 (as set forth in *In re Bilski*, 545 F.3d 943, 949 (Fed. Cir. 2008)), held patent ineligible in *Bilski v. Kappos,* 561 US 593 (2010)), which would be patent ineligible under § 101(b) as lacking any application of technology:

"A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:

"(a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;

The term "technology" is used in § 101(b) to confine patenting to inventions contributing to the "useful arts" as distinguished from human endeavors in the aesthetic arts and literary arts. In such areas, the copyright statute affords protection to the authors of such non-technological creations. The imposition of an "application of technology" standard injects a renewed vitality into the longstanding doctrine of patent law that prevents the issuance of valid patents where the alleged contribution of the invention to a useful art is based on *printed matter* or like human-intelligible information content.

Thus, where a claimed invention consists of placing an algorithm-determined sequence of numbers on an object such as a piece of jewelry (*e.g.*, a bracelet), the absence any contribution to a *useful* art would render the subject matter (*e.g.*, bracelet with on which the particular sequence of numbers appears) patent ineligible.[42] Thus, a claimed invention would not be eligible for patenting under § 101(b) even where the claimed invention evidences a high degree of creativity in contributing to a non-technological area of human endeavor, *e.g.*, where "[t]he stated object of the disclosed invention is to exploit certain arithmetic properties of all prime numbers larger than [a given number], to create the semblance of magic or to educate with respect to intriguing aspects of number theory" in specifying the sequence of numbers appearing on a bracelet.[43]

Claims with steps written in such a general or broad manner so as *not* to exclude the possibility that the steps could be performed mentally similarly require special scrutiny under the requirement that useful inventions must constitute a practically

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"(b) identifying market participants for said commodity having a counter-risk position to said consumers; and

"(c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions."

[42] See claims 1 and 5 of U.S. Patent 4,416,633:

"1. An educational and recreational mathematical device comprising at least one band which is endless or adapted to have ends thereof fastened to form an endless band and a plurality of individual digits imprinted on the band at regularly spaced intervals, the digits when all read consecutively clockwise as a number constituting a quotient obtained by dividing a number constituted of (P-1)/n nines, in which P is a prime number greater than 5 and n is an integer at least 1, by P and adding to the left-hand end of said quotient any number of zeros necessary to increase the number of digits in said quotient to (P-1)/n, n being so selected that (P-1)/n nines is the minimum number of nines divisible by P so that said quotient is an integral number." …

"5. Device according to claim 1 in which said band is an article of jewelry."

[43] *In re Gulack*, 703 F. 2d 1381, 1382 (Fed. Cir. 1983). The decision of the Federal Circuit holding Gulack's claim 1 to be patentable would be overruled under § 101(b) on the ground that human-intelligible information (*e.g.*, printed matter) alone cannot constitute specific and substantial contribution to a *useful* art where the subject matter being claimed fails to evidence any application of technology to an area of human endeavor.

useful application of technology. For example, an entirely mental process, *i.e.*, a process with each step drafted in such general or broad terms so as not to exclude the possibility that the steps could be performed mentally, would be categorically ineligible for patenting under § 101(b).[44]

Individual steps of a process claim reciting generalized language to describe acts to be performed, *e.g.*, *assessing, calculating, comparing, determining, identifying*, and *initiating,* would invariably raise the issue of whether the subject matter as a whole being claimed has been limited by sufficient non-mental acts so as to constitute a practically useful application of technology. In this respect, judicial holdings that require more than the application of human intellect itself for a claimed invention to be patent eligible are codified in § 101(b).[45]

The term "technology" as used in § 101(b) similarly limits patent protection if the subject matter being claimed contributes solely to the liberal arts more generally, whether those arts relate to economics and other social sciences or mathematics or the natural sciences. Thus, relationships, phenomena, schemes, laws, theses, algorithms, ideas, or concepts otherwise will fail to represent patent-eligible subject matter under § 101(b) notwithstanding that technological applications of such concepts can qualify as patent-eligible.

The application-of-technology requirement provides inherent limitations on the manner in which computer software-implemented inventions can be claimed, *i.e.*, the nature of the limitations on those claims required for patent eligibility. While the practically useful technological applications of software implemented in the form of a process, machine, manufacture, or composition of matter can represent subject matter eligible for patenting, *software as such* is an intellectual creation, *i.e.*, it is merely the instruction set to be performed by a computing machine. Thus, software as such is neither an application of technology nor does it become one simply by virtue of its use on a general-purpose computer.[46]

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[44] The holding of the Supreme Court in *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) that "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work" would be codified, with the caveat that applications of technology that are based upon or incorporate a phenomenon could be patent eligible.

[45] *In re Comiskey*, 554 F.3d 967, 980 (Fed.Cir.2009), holds that "the patent statute does not allow patents on particular systems that depend for their operation on human intelligence alone, a field of endeavor that both the framers and Congress intended to be beyond the reach of patentable subject matter. Thus, it is established that the application of human intelligence to the solution of practical problems is not in and of itself patentable."

[46] 1325 (Fed. Cir. 2016): "Software is a form of language—in essence, a set of instructions. See *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 447 (2007) (explaining that 'software' is 'the set of instructions, known as code, that directs a computer to perform specified functions or operations'

(5) AMERICA INVENTIONS ACT TECHNICAL CORRECTIONS

> *(A) JOINT INVENTORS.—In sections 102(b)(1)(A), 112(a), and 291(b), strike "or joint inventor" and insert "or a joint inventor".*
>
> *(B) ASSIGNEE FILERS.—In section 119(e)(1), in the first sentence, strike "by an inventor or inventors named" and insert "that names the inventor or a joint inventor" and in section 120, in the first sentence, strike "names an inventor or joint inventor" and insert "names the inventor or a joint inventor".*
>
> *(C) MORE APT PREAMBLE.—In section 102(a) strike "A person shall be entitled to a patent unless" and insert "A patent for a claimed invention may not be obtained if".*

A set of three technical corrections are made to the provisions of made in H.R. 6621 in the 112th Congress (Pub. L. 112-274, 126 Stat. 2456-2459). The amendments correct drafting errors or oversights in the America Invents Act as originally enacted and provide a more apt preamble to 35 U.S.C. § 102(a)(1) in recognition that the preamble enacted under the AIA failed to provide an antecedent for the term "claimed invention" used in the statutory text following the preamble. Under this amendment, the preambles for 35 U.S.C. § 102 and § 103[47] are made consistent.

(citations and internal quotation marks omitted)); see also 17 U.S.C. § 101 (defining a 'computer program,' for purposes of the Copyright Act, as 'a set of statements or instructions to be used directly or indirectly in a computer in order to bring about a certain result'). It is inherently abstract because it is merely 'an idea without physical embodiment,' *Microsoft*, 550 U.S. at 449 (emphasis added). Given that an 'idea' is not patentable, see, e.g., *Benson*, 409 U.S. at 67, and a generic computer is 'beside the point' in the eligibility analysis, *Alice*, 134 S.Ct. at 2358, all software implemented on a standard computer should be deemed categorically outside the bounds of section 101.

[47] The introductory clause of § 103 under the America Invents Act reads: "A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if… . The amended preamble for amended § 102(a) reads: "A patent for a claimed invention may not be obtained if… ."

Questions for the Record for Robert A. Armitage
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?

RESPONSE: Yes, a congressional fix is needed; no, the courts are not actually working this issue out, but are instead continuing to struggle with a vague and arbitrary standard for subject matter eligibility for patenting under an unworkable and unsalvageable non-statutory doctrine that Congress should abrogate.

Supreme Court Justices could hardly be unaware that certain aspects of the operation of the U.S. patent system have long been troubled. The *patent troll-patent extortion* scenarios that have played prominently in the media have painted the patent system in a bad light. Complaints by leading technology companies have asserted that patents are being issued with claims that offer at best only inconclusive clues has to how the owners of such patents might someday assert them. These are the headlines that amplify a sense, fair or not, that *there is something rotten with the state of the patent system* scenario.

These critics and these criticisms of the patent system—as I have often commented—are not *irrational*. Congress should not dismiss them as mere rantings. Quite the contrary. The critics are reacting to what they are seeing in their business—and what they are seeing can be an unpretty picture.

In the case of the conduct of certain patent assertion entities, the cost of acquiring a patent with at best questionable claims is virtually nil compared to the time, expense, uncertainty, and risk for an infringer to determine if paying tribute to the patent owner is justified. Patents—and the aggregation of patents into large portfolios—should not produce an economic value that is almost wholly dependent upon the time, expensive, uncertainty, and risk of demonstrating such patents unworthy of respect, because they are invalid or—if properly understood—would not be infringed.

The Supreme Court, looking at patents in *Bilski*, *Mayo*, *Myriad*, and *Alice* molded a simplistic response in finding "patent ineligibility" was a common culprit. Drawing on earlier precedents, the Court further contorted concepts from earlier cases to produce a metaphysical inquiry: Is the patent's claim *directed to a law, phenomena,*

or idea? If so, does the claim provides *significantly more* in the way of some *inventive concept*? If not, then the claimed invention is implicitly ineligible for patenting.

In practice, what the Court is mandating as a patent eligibility test is analytical hogwash. There is no way in which to apply this *directed to* test that is more than a vague and arbitrary inquiry.

Similarly, in 1952, Congress superseded the judicial holdings that *inventiveness* should be a requisite for patentability with a new statutory requirement for non-obviousness. They did so because *inventiveness* was a hopelessly elastic test with the capacity to arbitrarily invalidate any patent—a mere test of convenience.

Once the Supreme Court's overtightened the screws on patent eligibility, there is no real avenue for the lower courts to loosen them enough to blunt their inherent arbitrariness. For the Court itself, the one avenue of retreat that would make the most sense is outright *abrogation*. The Court could permit the remaining requirements for patentability fix the issues that beset the patent system—because other provisions of the patent statute were built by Congress to prevent patenting of any law/product of nature, natural/physical phenomenon, or idea of any type, including abstract ones—novelty, non-obviousness, disclosure sufficiency, claiming definiteness, and practical utility were put into the statute to assure that only a properly defined and confined process, machine, manufacture, or composition of matter could ever be validly patented.

However, naked abrogation by the Supreme Court is unlikely absent a guarantee that these remaining requirements for patentability are up to the task of righting the wrongs in the patent system's current operation. In any single appeal, the Supreme Court is not equipped to down regulate its over-tightened limits on patent eligibility law and secure any needed up-regulation of the law limiting how broadly patents can protect inventions.

What the Supreme Court cannot readily do is precisely what Congress is most able to do: undertake a process, such as that undertaken in the three hearings before the Subcommittee, that looks at the issues with the operation holistically. Congress can—through the testimony of 45 witnesses—gather together all the pieces of the puzzle of a patent system that has come to have dysfunctional aspects. It can then determine—all the puzzle pieces in hand—whether there is a way to put those pieces together to produce a picture of a patent system properly balanced to best promote progress in useful arts.

The lesson from 45 witness over three days of hearings is that any congressional effort to address on patent eligibility—*what* can be patented—must also address the companion question of *to what extent*—how broadly should an inventor be entitled to claim an invention?

If that is the lesson learned, then the present task before Congress was two-fold: abrogate and then remediate. Congress should address both the *what* and the *to what extent* questions in tandem. Doing so is essential to produce a balanced, principled outcome accommodating a broad spectrum of interests in the U.S. patent system. Those interests include freeing inventors to innovate with assured protection across all fields of technology, but not at the expense of affording inventors preemptive claims that go well beyond any subject matter actually conceived by the inventor and revealed in the inventor's patent filing.

To place all of this substance and nuance at the feet of nine justices of the U.S. Supreme Court when it is clearly the constitutional calling of Congress would be an abdication congressional responsibility in an area where three days of hearings have established that the interests of the United States would be best served by action.

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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"?**

RESPONSE: The purpose of introducing a "field of technology" test into the patent statute should be as part of a comprehensive effort to codify in the statute itself—in clear terms—all of the limitations that ought to apply to the patenting of a process, machine, manufacture, or composition of matter. The four terms—process, machine, manufacture, and composition of matter— define the only *categories* of subject matter that an inventor can claim. The patent statute already specifies that only a *new* process, machine, manufacture, or composition of matter can be patented. Similarly, the patent statute already dictates that only a *useful* process, machine, manufacture, or composition of matter can be eligible for patenting, with the term "useful" meaning some specific and substantial usefulness. This is usefully termed the requirement for a *practical utility*.

For machine, manufacture, or composition of matter to be new, it must be something built or constructed that differs from something already in existence, including anything already existing in the natural world—and practically useful. Implicit in the requirement that an invention claimed in a patent be *practically useful* is that the *useful arts* are benefited—progress is promoted in the useful arts.

As an example of a *manufacture* that is not *practically useful* in the context of the *useful arts* is a book that is asserted to be a *new* manufacture because it contains a set of novel recipes for baking better cookies. The novel arrangement of ink on the

pages of the book, however useful as conveying information that can be used to prepare cookies that might be less expensive to bake, be better tasting, or provide unexpected health benefits—all of which might be *practical benefits* of the new recipes should not qualify this *new manufacture* as eligible for patenting under the *usefulness* requirement.

In this example, the new manufacture makes no contribution to any useful art. While the information in the book does—and the information may be entirely new—there is no advance in the bookmaking art (clearly a *useful art*) that results from publishing a book containing novel information—however useful.

The current patent statute does not fully capture any of the subtlety that arises from the constitutional limitation on reach of the patent system—Congress is authorized to enact a patent law to promote progress in useful arts. It is for this reason that Congress should consider fully codifying this *useful arts* limitation.

In my response to questions from Chairman Tillis, I have proposed patent-eligible inventions be limited to those *making a specific and substantial contribution the useful arts through a practically useful application of technology to a field of human endeavor*.

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?

RESPONSE: In none of these jurisdictions is the issue of subject matter eligibility for patenting the subject of any great controversy. None have had the need for judicial intervention to impose an "implicit exception" to what is in the patent statute. All have patent systems that serve to promote progress in useful arts. Their experience suggests that abrogation of the "implicit exception" imposed by the courts here can both serve the constitutional purpose for the U.S. patent system and, thereby, be a constitutional exercise of the power of Congress to make the patent laws.

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?

RESPONSE: See my response to Chairman Tillis' questions where I offer a complete analysis of why the language I have proposed for an *application of technology* standard would codify a standard under which the Bilski claims would be patent ineligible, even if limited generically to being performed "on a computer."

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

RESPONSE: As outlined in my response to Chairman Tillis' questions, I would propose the following changes to 35 U.S.C. § 101:

> *RIGHT TO PATENT ELIGIBLE SUBJECT MATTER; PRACTICALLY USEFUL APPLICATION REQUIRED.—In section 101, strike and insert:*
> ***"§ 101. Right to patent eligible subject matter; practically useful application required.***
> *"(a) RIGHT TO PATENT ELIGIBLE SUBJECT MATTER.—Whoever invents or discovers any process, machine, manufacture, or composition of matter, or any improvement thereof, shall be entitled to a patent therefor, absent a finding that one or more conditions and requirements of this title have not been met.*
> *"(b) PRACTICALLY USEFUL APPLICATION REQUIRED.—No claimed invention may be regarded as eligible for patenting under subsection (a) that does not make a specific and substantial contribution to a useful art through a practically useful application of technology to an area of human endeavor."*

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?

RESPONSE: No. If my proposed formulation requiring that there be a specific and practical contribution to a useful art through an application of technology to an area of human endeavor, it would supersede any possible need for adding specific exclusions and would prevent granting patents with claims directed to genes as they exist in the human body, tax strategies, and human organisms.

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?**

RESPONSE: Any answer that I might offer to this question would be beyond my direct experience. I can offer a bystander's approach that is largely informed not through my experience as a patent attorney, but from discussions with patent professionals and my own experience writing computer software programs. The short answer would be "yes." The complaints appear to be valid.

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

RESPONSE: There have been several suggestions that have been made to making 35 U.S.C. § 112 operate more consistently and effectively across all areas of technology. In my response to Chairman Tillis, I have summarized what I believe to be an optimal set of legislative initiatives to take up whatever slack amending § 101 might create in rigorously employing the patentability requirements to keep the patent system in an appropriate balance between inventor exclusivity and competitor freedom of action. These changes would address any concerns of which I am now aware (after 44 witnesses other than I have testified) with abrogating the Supreme Court's "implicit exception" jurisprudence.

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

RESPONSE: Not in the least. The proposal to amend 35 U.S.C. § 112(f) leaves inventors with a broad scope protection when their inventions have been described an enabled in commensurately broad terms. The inclusion of protection for "equivalents" under § 112(f) then frosts this cake. It may, however, be relatively easy for competitors to design around patent claims of inventors whose patent disclosure—and contribution to the art—is relatively skimpy. I find that, however, to be unconcerning.

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?

   RESPONSE: The amendments to 35 U.S.C. § 101 should have no conceivable impact on the doctrine of obviousness-type double patenting. Under current law, § 101 imposes a same-invention double patenting bar. Under this bar, a second patent cannot be granted on the same or substantially the same claimed invention. If a second, later-issued patent claims the "same invention," then the second patent is invalid under § 101 because it only authorizes "*a* patent" on an invention. All proposed amendments to 35 U.S.C. § 101 would continue to contain an identical "*a* patent" limitation.

On the other hand, obviousness-type double patenting is an entirely judge-made doctrine. It addresses the situation where two patents contain one or more claims for each patent that are highly similar to one or more claims of a second patent. Typically obviousness-type double patenting arises because the claims in neither patent is "prior art" to the claims of the other patent so that the requirement for non-obviousness under the patent statute (35 U.S.C. § 103) does not serve to simply invalidate the similar claims of one patent that are patentably indistinct from the claims of the other patent.

Obviousness-type double patenting is never an obstacle to secure a patent on minor changes in a drug because in any circumstance where the change in the drug is minor, the obstacle to patenting is *statutory* obviousness. Once a drug is in development, under the patent law it becomes *available to the public* so that when patents are subsequently sought for any change in the drug, the only patents that can issue on the improvement are those that are non-obvious in view of the subject matter already available to the public. Indeed, there are no examples of obviousness-type double patenting ever constituting a ground for denying a patent on a minor change to a drug that would not have been more facilely invalidated under the requirement for statutory obviousness.

That said, the patent law has provisions that are amenable to patent procurement strategies by anyone, biopharma companies included, that can extend the life of a patent beyond the 20-year—and do so by months to years. These are the "patent term adjustment" or PTA provisions in the patent statute.[1] Indeed, these patenting strategies can result in patent term adjustments—PTAs—that can extend well beyond any period of added patent life that might theoretically result from securing a "double patent." For example, under the new first-inventor-to-file law enacted in 2011, no claim in a "double patent" can have result in a patent term that expires later than 2 years the end of the 20-year term of other patent involved in the double patenting.[2] On the other hand, the statute providing for patent term adjustment can operate

[1] See *Strategies for Maximizing Patent Term*, http://www.fr.com/files/uploads/Maximizing%20Patent%20Term%20PowerPoint%20Presentation.pdf .

[22] This at least theoretical possibility exists if a patent were to issue to an inventor and the inventor were to wait one year after the patent issued to seek a "double patent" through a provisional patent application filing followed one year later by the filing of a nonprovisional patent application that would then issue for a 20-year term from the nonprovisional filing date, which would be two years after the issuance of the other patent. In real world scenarios, this would be unlikely because ability to make a second patent filing for the purpose of seeking a double patent is eliminated once the subject matter claimed in the other patent is public—or other public disclosures have been made the would independently render the claims of the double patent obvious.

to extend the life of any patent—not just a "double" patent—far longer than this 2-year period—on the order of a decade in extreme cases.[3]

The doctrine of obviousness-type double patenting should, therefore, be entirely unaffected by any of the proposals to amend § 101, including those that would abrogate the judge-made law creating an "implicit exception" to the subject matter that is eligible for patenting. That said, in the course of eliminating the judge-made "implicit exception," the hearings established the desirability to making significant reforms to the judge-made law creating a "research use exception" to patent infringement. The narrowness of that judge-made law has elicited testimony during the Subcommittee's hearings that the process of a legislatively addressing the judge-made "implicit exception" law also reform the judge-made "research use exception" law.

It would, therefore, not be unreasonable for the present process to include reforms to the judge-made law on obviousness type double patenting. An effort along these lines was made in H.R. 9 (114th Congress). See House Report No. 114-235, pp. 45-51. Since the efforts in 2015, more streamlined proposals have emerged for codifying essentially all of the law of obviousness-type double patenting. Moreover, to the extent Congress would be interested in working a simplification of the law—and reduce any potential for gamesmanship based on patenting strategies, it would be logical to simplify and streamline both obviousness-type double patenting and paten term adjustment as part of a package of changes to restore almost all issued U.S. patents to a simple 20-year patent term measured from the inventor's initial patent filing.

Foremost, Congress should consider, as an alternative to examining patent applications for obviousness-type double patenting and requiring enforceability-related disclaimers to be made in such applications before a "double patent" can issue, imposing a *statutory* patent enforcement bar with respect to any patent that was determined to be a "double patent" and having that statutory patent enforcement bar replace the current judge-made law of obviousness-type double patenting for all first-inventor-to-file patents. Similarly, Congress should limit the effect of such an abrogation of the judge-made obviousness-type double patenting law for first-to-invent patents, all of which have patent terms calculated under the 20-year, filing-date-based patent term under the Uruguay Round Agreements Act to a requirement for disclaimer of separate ownership or separate enforceability in order for any claim of a patent representing double patenting to be held valid. Finally, assuming these reforms are made, Congress should eliminate the current "patent term adjustment" provisions that can encourage patent applicants to adopt patent prosecution strategies that can extend the 20-year patent term for months to years. Through such a collection of

[3] See U.S. Patent 8.622,633 that indicates on its face: "Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 3497 days."

reforms, essentially every patent issued would have a 20-year patent term , simply calculated at from its earliest patent-filing date, without exception, and essentially all obviousness-type double patenting issues going forward would be addressed by the courts, by limiting enforcement of "double patents."

A statutory provision limiting enforcement would amend 35 U.S.C. § 281 by striking and inserting:

"§ 281. Remedy for infringement of patent.

"(a) In General—The patentee shall have a remedy by civil action for infringement of the patentee's patent.

"(b) Double Patents; Indispensable party.—

"(1) In general.—Notwithstanding subsection (a), a civil action for infringement that has been brought with respect to either of two double patents may be maintained only if the action would not have been barred by res judicata had each of the claims of the two patents issued jointly to the respective patentees of the two patents in a single patent.

"(2) Indispensable party.— The patentee of one of two double patents, who would be barred by res judicata under the preceding paragraph as a consequence of a civil action brought to enforce the other of the two patents, shall be an indispensable party to such civil action.

"(3) Double patents defined.—For the purposes of this subsection, the term "double patent" shall mean either of two patents in which—

"(A) for at least one pair of claimed inventions, one selected from each of the two patents, neither claimed invention constitutes prior art to the other under section 102(a)(2), taking into account the exceptions under section 102(b)(2); and

"(B) for at least one pair of claimed inventions under subparagraph (A), where neither is prior art to the other, one of the claimed inventions would have been obvious under section 103 in view of the other, had the other constituted prior art to it under section 102(a)(2).

This amendment would apply only to patents that are subject to the first-inventor-to-file provisions under the Leahy-Smith America Invents Act. New § 281 consists of two subsections. New § 281(a) is substantively unchanged from the repealed § 281. The only difference between the new text of § 281(a) and the repealed text of § 281 is that the possessive noun "patentee's" is substituted for the pronoun "his" to render new subsection (a) gender-neutral. New § 281(a) reaffirms that patent owners have the right to bring a civil action as a remedy for infringement of their respective patents.

Subsection (b) of § 281imposes new limitations on the enforcement of certain first-inventor-to-file patents, defined in § 281 as "double patents." It does so by limiting in certain circumstances the right to bring a separate civil action on one of two double patents once the once the other of the two double patents has been the subject of a separate cause of action for patent infringement. Additionally, it

imposes a new "indispensable party"[4] requirement on double patents that are not owned by the same patentee. The new limitations relating to such enforcement-linked patents have no counterpart in the current statute.

New subsection (b) consists of three paragraphs. The first paragraph is the one that bars certain civil actions involving double patents under a res judicata principle. The second paragraph then imposes the new requirement relating to the indispensable parties to a civil action alleging the infringement of such a double patent. The third paragraph defines the double patents to which the new res judicata bar and indispensable party requirements apply for first-inventor-to-file patents apply.

The overall objective of new § 281(b) is to link the enforcement of a first-inventor-to-file patent with another patent containing at least some *patentably indistinct* claims. The enforcement linkage, if such patents are separately owned or become separately owned, prevents multiple civil actions alleging infringement of double patents to be brought by separate patentees who might otherwise be entitled to separate damages, thereby eliminating any potential for harassment arising from patentably indistinct claims. Eliminating the potential for such harassment obviates one of the two justifications for the imposition by the courts of the non-statutory "double patenting" grounds for invalidating patent claims.[5]

Under new § 281(b)(1), a civil action for infringement, once brought, may be maintained with respect to a double patent only if the new "res judicata" requirement set out in this paragraph is satisfied. Under this new requirement, such a civil action with respect to a double patent may not go forward if the allegations of infringement therein would have been barred by res judicata had both double patents instead issued as a single patent, *i.e.*, had each of the claims of the asserted patent and the other of the two double patents been originally issued as a single patent that was granted to jointly to the respective patentees (or, in the case of commonly owned patents, the common patentee) of the two patents.

Thus, a civil action can only be barred under new paragraph (1) in the circumstance where the two patents containing patentably indistinct claims would not have supported multiple causes of action under the established

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[4] Under Rule 19(b) of the Federal Rules of Civil Procedure, an "indispensable party" is a "necessary party" to a civil action under Rule 19(a) who, if unable to be joined as a party to the action, mandates dismissal of the lawsuit. See *A123 Systems, Inc. v. Hydro-Quebec*, 626 F. 3d 1213, 1220 (Fed. Cir. 2010), dismissing a § 281 civil action based on the failure to join the patentee who "was not only a necessary party but also an indispensable party, making dismissal appropriate."

[5] In this regard, the Federal Circuit has "recognized a 'concern over potential harassment of an infringer by multiple assignees asserting essentially the same patented invention…'" *In re Hubbell*, *supra*, at 709 F. 3d 144.

principles of res judicata, but for the issuance of such claims in two patents instead of a single patent. In this respect, the new limitation on civil actions with respects to enforcement linked claims vindicates the policy objective under non-statutory "double patenting" principles without the need for intervention by the United States Patent and Trademark Office to condition the grant of patents with indistinct claims on maintaining common ownership of the patents with such claims—or disclaiming the right to separately enforce two such patents.

Under new § 281(b)(2), a patentee who would be barred by res judicata under paragraph (1)—as a consequence of a civil action brought to enforce one of two double patents—is made an indispensable party to such civil action brought to enforce the other of the two double patents. This new requirement removes any possibility that one of the two patentees holding double patents could be denied the remedy of a civil action to enforce its patent because of a unilateral infringement action by the other patentee had triggered the res judicata bar under § 281(b)(1).

Most commonly, double patents will be commonly owned, and the indispensable party requirement will only apply if ownership of one of the two patents has been subsequently alienated—with such alienation representing an action that has been heretofore barred under the terminal disclaimer practice under 37 C.F.R. § 1.321I relating to commonly owned patents. Under 37 C.F.R. § 1.321I, the United States Patent and Trademark Office requires a "terminal disclaimer" in the situation where the two patents involved in the "double patenting" are commonly owned that requires maintenance of such common ownership for the disclaimed patent to remain valid. This rule specifically requires "any patent granted … shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting."

In the case of patents subject to non-statutory double patenting that were not initially commonly owned, 37 C.F.R. § 1.321(d) imposes a similar requirement to effectively bar separate enforcement. For these patents, the USPTO rule requires "waiving the right to separately enforce any patent granted on that application … and the patent … which formed the basis for the double patenting, and that any patent granted … shall be enforceable only for and during such period that said patent and the patent … which formed the basis for the double patenting are not separately enforced." Subsequent to the enactment of the Leahy-Smith America Invents Act, both patentees of the two separately owned patents must jointly disclaim separate enforcement for the double patent for the

USPTO to accept the terminal disclaimer as being legally sufficient to redress the double patenting.[6]

With the enactment the amendment in subsection (b), enforcement-related disclaimers required under 37 C.F.R. § 1.321 for first-inventor-to-file patents would be superseded by the enforcement-related limitations in 35 U.S.C. § 281(b). In combination, §§ 281(b)(1) and (2) remove the any basis for continuing to require such disclaimers relating to continued common ownership or separate enforcement with respect to first-inventor-to-file patents. Together, these two paragraphs preclude any possibility that two double patents, *i.e.*, patents containing patentably indistinct claims, could be separately enforced in a manner that could be regarded as harassment by multiple patentees.

Under paragraph (3), a definition is provided for a "double patent." The definition imposes two separate requirements that must be met by each of a pair of patents for the two patents to be regarded as double patents. Those requirements appear in separate subparagraphs, *i.e.*, subparagraphs (A) and (B).

Under subparagraph (A), the first of the two requirements is met if, for at least one claimed invention selected from each of two patents, neither such claimed invention constitutes prior art under 35 U.S.C. § 102(a)(2) to the other. If each claimed invention of either of the patents is prior art to each of the claimed inventions of another patent, neither patent constitutes double patent with respect to the other. In such a circumstance, none of the limitations of new § 281(b) apply to either patent.

In general, therefore, the requirement under subparagraph (A) will not apply unless patent applications were filed on the same day (*i.e.*, neither is "prior" to the other and cannot constitute "prior art") or one of the exceptions to prior art set out in 35 U.S.C. § 102(a)(2) or § 102(b)(1) apply. These exceptions are limited to claimed inventions (1) in patents naming the same inventor or joint inventor or (2) that were commonly assigned or (3) subject to a joint research agreement.

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[6] For a discussion of the disclaimer of the right to separately enforce patents, see H.R. Rep. No. 108-425 at p. 6 and the Hatch colloquy at Cong. Rec. S7521 (June 25, 2004), discussing the requirements of a disclaimer relating to separate enforcement as part of the legislative history of the Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Pub. L. No. 108-453, 118 Stat. 3596, which permitted separately owned patents with patentably indistinct claims to be validly issued, subject to such disclaimers: "To meet the requirements of the [CREATE Act], the parties to the joint research agreement must agree to accept the conditions concerning common term and the prohibition against separate patent enforcement *and all involved parties must agree to be signatories to any required terminal disclaimer*." [Emphasis supplied.] Under the Leahy-Smith America Invents Act, Pub. L. 112-29, 125 Stat. 284, the above requirement expressed in the CREATE Act legislative history has been enacted into law. See AIA § 3(b)(2), "The United States Patent and Trademark Office shall administer section 102(c) of title 35, United States Code, in a manner consistent with the legislative history of the CREATE Act that was relevant to its administration by the United States Patent and Trademark Office."

Under subparagraph (B), the second of the two requirements is met if a modified form of the so-called "one-way" test[7] for determining if the claims of a patent represent "obviousness-type" double patenting by undertaking a claim-to-claim comparison as between respective claims of the two patents.[8] However, subparagraph (B) modifies this "one-way" test by considering each of the claimed inventions being assessed for patentable distinctness as though they were prior art under § 102(a)(2) to the other. For the purpose of applying paragraph (3), the term "claimed invention" refers to the subject matter defined by the claim.[9]

Under § 281(b)(3)(B), the patentable distinctness in light of such assumed "prior art" is assessed through a statutory obviousness analysis under 35 U.S.C. § 103. Thus, subparagraph (B) provides that, for each claimed invention that forms a pair of claimed inventions in which neither claimed invention would otherwise be prior art to the other under subparagraph (A), the modified "one-way" test is satisfied if one or more of such claimed inventions would have been obvious in view of the other as § 102(a)(2) prior art under section 103's requirement for non-obviousness.

Since the provisions of new § 281(b) to not apply to patent applications being examined or patents that have issued under the first-to-invent conditions for patentability, the examinations of such applications and the validity of any patents issued on such applications would continue to depend on a disclaimer of separate enforceability, including—when applicable—through a disclaimer of enforceability to the extent the patents involved in the non-statutory double patenting do not remain common owned. As noted above, however, such requirements for disclaimer are superseded for all patent applications—and patents issued on such applications—that have been, are being, and will be examined under the first-inventor-to-file conditions for patentability.

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[7] The Federal Circuit has used both a "one-way" and a "two-way" test to assess patentable distinctness of claimed inventions from each of two patents. The respective claims can be patentably distinct under the "one-way" test if obviousness would be found running the comparison of the claimed inventions "either way"—by considering either claimed invention prior art to the other to determine if obviousness would exist either way. In constrast, the claims of the respective patents can qualify as patentably distinct under the "two-way" test only of obviousness would be found running the comparison "both ways." The Federal Circuit has progressively limited the applicability of the more limited "two way" or "both ways" test for patentability indistinctness in favor of more expansive "one-way" or "either way" test. See *In re Berg*, 140 F. 3d 1428, 1432 (Fed. Cir. 1998), "Generally, a 'one-way' test has been applied to determine obviousness-type double patenting. … [W]hen the two-way test applies, some claims may be allowed [as patentably distinct] that would have been rejected [as patentably indistinct] under the one-way test."

[8] See *Geneva Pharmaceuticals v. GlaxoSmithKline*, 349 F. 3d 1373, 1385 (Fed. Cir. 2003), "because nonstatutory double patenting compares earlier and later claims, an earlier patent's disclosure is not available to show nonstatutory double patenting."

[9] This is the statutory definition for the term "claimed invention" found in 35 U.S.C. § 100(j).

With the enactment of the above enforcement limitation, Congress would be positioned to enact a statutory provision abrogating the doctrine where it would have no remaining policy justification. The text that would accomplish this abrogation could include the following:

"A claimed invention of a patent may not be held invalid with respect to a claimed invention of another patent based on any nonstatutory double patenting ground if one of the claimed inventions is prior art to the other claimed invention under section 102 of title 35, United States Code, or the claimed invention of the patent is subject to section 102 of title 35 as amended by the Leahy-Smith America Invents Act (Public Law 112–29; 125 Stat. 284)."

The provision above prevents any non-statutory double patenting ground for invalidity from being applied in two situations. First, no non-statutory double patenting invalidity can apply to a claimed invention in one patent based on a claimed invention in any other patent if either claimed invention is prior art to the other. The rationale for this limitation is that both claimed inventions can be validly patented only if the prior art invention does not render the other invention obvious under the existing statutory requirement for non-obviousness under 35 U.S.C. § 103. In the situation where statutory non-obviousness bars the issuance of two valid patents, there is no conceivable policy justification for nonetheless declaring either claimed invention to be double patenting.[10]

The second exclusion prevents non-statutory double patenting from applying to any first-inventor-to-file patent.[11] The amendments made under subsection (b) to 35 U.S.C. § 281 obviate any conceivable policy rationale for the courts to impose a non-statutory double patenting bar by imposing limitations on the enforcement of first-inventor-to-file patents that remove the potentially for harassment from infringement actions brought by multiple patentees seeking to enforce claims on patentably indistinct inventions.

A further amendment would prevent obviousness-type double patenting issues from impacting the patent term of patents subject to the Uruguay Round Agreements Act:

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[10] This provision would expressly overrule the recent expansion by the Court of Appeals for the Federal Circuit of non-statutory double patenting as reflected in *In re Hubbell*, 709 F.3d 1140 (Fed. Cir. 2013), which followed earlier holdings if the same ilk in *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) and *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly and Co.*, 611 F. 3d 1381 (Fed. Cir. 2010). In such cases, the court had held that double patenting was possible even though the statutory non-obviousness requirement under 35 U.S.C. § 103 would have assured that two valid patents could not have issued unless the claims of the respective patents had been patentably distinct.

[11] "First-inventor-to-file patents" is a reference to patents that are subject to the prior art provisions of 35 U.S.C. § 102(a) enacted in § 3(b) of the Leahy-Smith America Invents Act (Public Law 112–29), 125 Stat. 284.

"If the term of a patent is based upon the amendments made to subsection (a) of section 154 by the Uruguay Round Agreements Act (Public Law 103–465; 108 Stat. 4809)—

"(A) the patent term as provided under subsection (a) of such section 154, United States Code, any adjustment to said term as provided under subsection (b) of such section 154, and any extension of such term as provided under section 156 of title 35, United States Code, shall not constitute and must not be deemed by the United States Patent and Trademark Office or the courts to constitute, an unjustified period of protection under the patent, or an unjustified extension of the right to exclude under the patent, relative to any earlier-expiring patent; and

"(B) the Office may not condition the issuance of any such patent on a disclaimer of the terminal part of the patent term otherwise permitted under sections 154 and 156, United States Code.

Under this provision, two rules of construction are provided in subparagraphs (A) and (B). As noted above, each of these provisions applies only to patents that have terms of protection determined under the Uruguay Round Agreements Act (Public Law 103–465; 108 Stat. 4809), *i.e.*, have a statutory patent term under 35 U.S.C. § 154(a) that ends 20 years after the original, nonprovisional filing date of the patent application, subject to any patent term adjustment or patent term extension that might be justified under § 154(b) or 35 U.S.C. § 156.

Subparagraph (A) bars either the United States Patent and Trademark Office or the courts from deeming the available statutory exclusivity for a patent subject to the URAA to produce an unjustified timewise extension of such exclusivity relative to the term of any other issued patent. This rule of construction assures a patent owner that the new statutory prohibition on considering patent exclusivity to be unjustified includes exclusivity based upon the 20-year patent term authorized under 35 U.S.C. § 154(a), as well as any adjustment to that term authorized under § 154(b) or any extension of that term under 35 U.S.C. § 156.

Since these provisions of the patent law authorize exclusive rights under any individual patent for the limited time for which Congress is authorized to provide for the grant of patents, Congress has directed under Section 3(c)(1) that there is no basis for the Office or the courts to limit or negate such protections for limited times on a non-statutory double patenting ground or otherwise. This rule of construction precludes the Office or the courts from determining that a claimed invention in any URAA patent is unpatentable or is invalid based upon the failure of a patent owner to disclaim the terminal part of the term of the patent.

Subparagraph (B) specifically addresses the "terminal disclaimer" practices of the United States Patent and Trademark Office to the extent those provisions are applied to URAA patents. It expressly bars the Office from conditioning the issuance of a URAA patent on disclaiming the terminal part of the term of such a patent.

This subparagraph overruling one aspect of the current USPTO disclaimer practice applies to the first-to-invent patents that remain subject to non-statutory double patenting. The first-to-invent patents that remain subject to non-statutory double patenting are those that contain patentably indistinct claims under non-statutory double patenting law as limited under Subsection (a) and, therefore, will remain subject to disclaimers of separate ownership or separate enforcement under 37 C.F.R. §§ 1.321(c) or (d)—but will no longer be subject to disclaimers of term pursuant to the amendments under subparagraph (B).

A fair proposal for amending the patent term adjustment statute would strike 35 U.S.C. § 154(b) and insert a provision limiting adjustments to "secrecy order" patents:

"(b) Adjustment of Patent Term.—If the issue of an original patent is delayed due to the imposition of an order under section 181, the term of the patent shall be extended 1 day for each day of the pendency of the order."

Section 154(b) is one of the most complicated provisions of the current patent statute, providing for patent term adjustment based on the length of time that a patent application remains pending in the United States Patent and Trademark Office prior to the issuance of a patent. Subsection (e) simplifies this provision by limiting patent term adjustment to secrecy orders under 35 U.S.C. § 181.[12]

Retaining an adjustment of term for secrecy orders only for secrecy orders is justified because the USPTO is barred from allowing the invention disclosed in a "secrecy order" application for patent from becoming public so long as a secrecy order remains in effect. Except in the case of a secrecy order, patent applicants have their applications published at 18 months from their priority filing date, at which point the patent owner has a statutory right to a reasonable royalty under 35 U.S.C. § 154(d)(1),[13] and the further option for prioritized or accelerated

[12] The first paragraph of § 181 provides "[w]henever publication or disclosure by the publication of an application or by the grant of a patent on an invention in which the Government has a property interest might, in the opinion of the head of the interested Government agency, be detrimental to the national security, the Commissioner of Patents upon being so notified shall order that the invention be kept secret and shall withhold the publication of an application or the grant of a patent therefor under the conditions set forth hereinafter."

[13] "In addition to other rights provided by this section, a patent shall include the right to obtain a reasonable royalty from any person who, during the period beginning on the date of publication of the application for such patent under section 122(b), or in the case of an international

examination as a means of securing and prompt issuance of an originally filed application for patent. Section 2(a)(2) codifies the right of patent applicants to secure an accelerated examination under procedures that are currently provided by USPTO regulation[14]

These opportunities for patent applicants to secure prompt patent issuance obviate the need for non-secrecy-order patent applicants to be given an adjustment of term in order to secure the possibility for adequate remuneration through the patent filing. No patent applicant will have the opportunity for less than an 18.5-year to 19.5-year period of protection based upon a patent filing. This 18.5-year to 19.5-year period represents the combination of the pre-grant, post-publication period when reasonable royalties are available and the post-grant exclusivity period.

Use of the procedures for accelerated or prioritized examination now available in the USPTO will typically result in a nearly 18- to 19-year post-issuance exclusivity period. These periods are substantially in excess of the 17-year protection period available prior to the Uruguay Round Agreements Act that the patent term adjustment provisions in § 154(b) were intended to simulate. Hence, no policy justification remains for maintaining these complicated provisions of the patent statute (other than in the case of secrecy orders) given their potential to encourage patent prosecution strategies that serve to delay the final resolution of patentability issues in connection with a patent filing.

By combining the elimination of patent term adjustment with the elimination of any requirement for disclaimers based upon obviousness-type double patenting, Congress can restore the patent law to the simplicity of granting all U.S. patents for the 20-year period starting on the date of the inventor's initial, non-provisional patent filing. The only exceptions to this rule would be the miniscule number of patents that might have different terms due to secrecy orders under 35 U.S.C. § 181 or regulatory review periods under 35 U.S.C. § 156.

Because, going forward, all new patent filings will be first-inventor-to-file applications subject to the Uruguay Round Agreements Act, such that no patent examining resources would need to be examined for obviousness-type double

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application filed under the treaty defined in section 351(a) designating the United States under Article 21(2)(a) of such treaty, the date of publication of the application, and ending on the date the patent is issued … makes, uses, offers for sale, or sells in the United States the invention as claimed in the published patent application or imports such an invention into the United States; … and … had actual notice of the published patent application and, in a case in which the right arising under this paragraph is based upon an international application designating the United States that is published in a language other than English, had a translation of the international application into the English language."

[14] See https://www.uspto.gov/patent/initiatives/usptos-prioritized-patent-examination-program and https://www.uspto.gov/patent/initiatives/accelerated-examination.

patenting, no processing of disclaimers would be necessary, and no adjustments to patent terms would be needed.

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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?

RESPONSE: Congress should take seriously the Takings Clause implications of the retroactive application of any aspect of the patent statute that would diminish in any respect the exclusive rights granted to the owner of a patent.

In my testimony, I included an appendix that proposed a transition provisions would obviate any Takings Clause issue by affording every patent owner a 6-month period after enactment to opt-out of the applicability of the new standards defining patent eligibility and other aspects of patentability in the legislation. In my view, such a provision would moot any Due Process/Taking Clause issues.

Questions for the Record for Mr. Robert A. Armitage
Senate Committee on the Judiciary
Subcommittee on Intellectual Property
Hearing on "The State of Patent Eligibility in America: Part I"
June 4, 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?**

RESPONSE: The prime justification for the patent system is that it provides incentives that are essential for securing investments required to develop and commercialize new technology. Using lessons learned from watching "Shark Tank," patents work to promote progress in useful arts when they secure capital for investments in the development and commercialization of new technology that otherwise would not take place. Put another way, any protections Congress enacts for consumers should not be to protect them from innovative products that can never get to market.

The problem with the Supreme Court's subject matter eligibility jurisprudence is not that it is too restrictive or too expansive, but that the test being mandated is too vague and too arbitrary. Congress should not be working with the sole purpose to broaden the subject matter that can be patented as much as it should see its primary take as assuring that the patent laws operate in a manner where the requirements for securing a valid patent are as transparent, objective, predictable, and simple as possible.

If the primary congressional goal is not *broadening*, but advancing transparency, objectiveness, predictability, and simplicity, then the impact on industry should be positive—both from participants that seek to invest developing patented technologies for the marketplace and those seeking freedom of action to market their own innovations, notwithstanding patent rights that others may have already secured.

I have supported the Subcommittee's efforts in large measure because, from the outset, those efforts have sought to balance greater certainty on subject matter eligibility issues with greater certainty on "scope of protection" issues—not just *what* might be patented, but *to what extent*. In response to questions from Chairman Tillis, I have outlined what I believe might represent a fully balanced approach to this legislation. If that approach is followed, I believe that industry will

benefit from a patent law with clearer standards, including greater clarity in the scope of protection that a valid patent can provide.

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

RESPONSE: Given the impact on industry is positive—more investment in more innovative products and more clarity as to the limitations on the scope of protection a valid patent can afford—the impact on consumers of the legislative efforts will be just as positive as the impact on innovators. A better functioning patent system has a proper balance between protection and freedom of action and should produce more innovation and more competition for innovation, thereby doubly benefitting consumers.

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

RESPONSE: The only *long-term* effect the patent system has ever had on consumer prices is to reduce them. This is because the long-term effect of the patent system is to place the inventions claimed in expired patents into the public domain, where they can be freely copied. Where use of the patent system has resulted in an innovative product being developed for the market, and then successfully commercialized, the patent system will have established a market for the one-patented product that a copier need not develop from scratch. In short, over the long term, consumer benefits from patent-induced incentives to develop and commercialize new technology include, among other benefits, price benefits. One need only look to the trillions of dollars in consumer savings attributable to the generic drug industry to see how strong patent protection has a long-term downward effect on price.

In a similar vein, the only short-term effect that a *valid patent* has ever had on consumer prices is to reduce them. Necessarily, a *valid patent* is a patent granted on a technological innovation that theretofore did not exist—and, thus, was unavailable to the consumer at any price. To use a trivial example, the price of sending a telegraph after Samuel Morse's invention was vastly less expensive than any effort to telegraph a message before that invention was made.

Thus, in my opinion at least, the only economic consequence of *good patent legislation* is that it inherently operates across all technology sectors to reduce consumer prices—either by affording consumers access to technology theretofore unavailable at any price or by affording free-for-all competition once the limited term of a patent has expired—or by forcing competitors into the creation of new technology that has successfully designed around an existing patent and, thereby, created the opportunity for competition in the marketplace among the competing innovations.