

The U.S. patent system cannot credibly advance its constitutional purpose to promote progress in useful arts unless the patent statute is able to articulate, in a clear and predictable manner, both the *nature* of the subject matter that can be eligible for patent protection and the *extent* of the protection that will be afforded under a patent. These two most fundamental concepts of the patent law permit inventors to know “for what” and “to what extent” patent protection can be available.

The notion that only certain types of *subject matter* should qualify as eligible for patenting has never been in serious dispute. No one contends that laws, phenomena, or other ideas by themselves can be patented. Most commentators would concur that patents are for the *practically useful applications* of any laws, phenomena, or ideas to which an invention might relate. To that end, such patent-eligible applications must—by statute—be expressed in terms of a *process, machine, manufacture, or composition of matter*. If it ain’t *tangible*, it ain’t patent-eligible.

Under the notion that constraints must exist on the *breadth of available protection* for an invention, there is no serious dispute that the scope of protection under a patent should be *proportionate*. The permitted claim breadth should be based on the extent to which the inventor is able to *sufficiently describe in its patent filing* the subject matter meriting protection.

Considered separately, these notions of *tangibility* and *proportionality* are quite straightforward. They work in concert with the notion of *inventiveness*. The *inventiveness* principle demands that patentable inventions should be limited to subject matter that is both new and *more than trivially different from anything already made available to the public*.

In 1793, Congress first limited the “for what” circumscribing permitted patent protection to *processes (then “arts”), machines, manufactures, and compositions of matter*. The requirement that only *useful* subject matter could be patented is even older. The requirement that inventions must be “useful” has been part of all patent statutes since 1790. The courts have given this statutory *usefulness* requirement a constitutional dimension—it is a specific and substantial usefulness that is needed. Patents are for advancing the “useful arts”—setting a context in which usefulness should be measured.

On the “to what extent” notion, the Supreme Court has been clear—in its decisions addressing the statutory “disclosure-sufficiency” requirement—that the principle of *proportionality* rules. The Court has held that a claimed invention must be based on a sufficient disclosure, a requirement that invalidates patent claims that set out crucial elements in a functionally defined way—*i.e.*, in terms that would afford protection over all means for achieving a functionally defined end.

In addition, the Supreme Court—*apparently to address a growing concern with the U.S. patent system that claims were being granted to inventors affording patent protection over the broad concepts on which an invention was based*—has in recent years judicially imposed what has proved to be an amazingly unworkable requirement. It has invalidated patent claims, *as subject matter ineligible*, when the claims (1) are directed to a law of nature, natural phenomenon, or abstract idea and (2) fail to contain significantly more than the idea itself, specifically some *inventive concept*. The result of this jurisprudence has been a conflation of the law on subject matter eligibility with the statutory disclosure-sufficiency requirement (already guaranteeing *proportionality* for a valid claim) and the statutory non-obviousness requirement (already guaranteeing *inventiveness* for a valid claim).

A May 22 bipartisan, bicameral legislative proposal would end the Supreme Court’s conflation of patent eligibility with disclosure-sufficiency and non-obviousness statutes by (1) abrogating the Supreme Court’s conflating “implicit exception;” (2) codifying judicial precedents that the statutory term “useful” means *a specific and practical utility applied to an area of human endeavor in a field of technology*; and (3) expanding the application of existing 35 U.S.C. § 112(f) that assures proportionality by limiting what a functionally defined claim might cover.

This statutory intervention by Congress would brilliantly address the concerns expressed by each of the various constituencies affected by the operation of the U.S. patent system. It improves the manner in which the United States Patent and Trademark Office and the courts can regulate the breadth of patent coverage when the inventor has claimed an invention in functional and potentially preemptive terms, while at the same time freeing inventors to pursue all manner of claims directed to a practically useful process, machine, manufacture, or composition of matter contributing to a useful art.

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Statement of
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Before

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Committee on the Judiciary
Subcommittee on Intellectual Property

On

The State of Patent Eligibility in America: Part I

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Opening Overview – Oral Statement

Chairman Tillis, Ranking Member Coons, and members of the Intellectual Property Subcommittee, I want to thank you for your efforts and those of your staffs in organizing and conducting these three days of hearings on the State of Patent Eligibility in America.

The state of patent eligibility law in the United States is tragically bad. The Supreme Court has acted unwisely in augmenting the statutory requirements for securing a valid patent with a judicially imposed “implicit exception” to the subject matter that can be regarded as eligible for patenting.

The Court’s mandated two-part test¹ for determining patent eligibility has proven unworkable in practice. It has yielded incoherent and unpredictable results.

Indeed, had Congress placed into the patent statute itself the test that the courts now mandate must be applied, the Supreme Court might be obliged to hold such a statutory standard impermissibly vague and arbitrary—and be forced to declare a legislated incarnation of the Court’s own “two-part test” a violation of the Due Process clause of our Constitution.

The Supreme Court was recently given a compelling opportunity to overrule its problematic precedents, namely through the certiorari petition in *Sequenom v. Ariosa*.² In *Sequenom*, more than a score of amicus briefs³ explained that, for the good of the patent system and of the country, the Court needed to remedy the manifest problems that its patent eligibility holdings had produced.

¹ Referenced herein, variously, as the *Mayo/Alice* test, *Mayo/Alice* framework, *Mayo/Alice* two-part test, or simply the two-part test. The latest incarnation of this test, as described by the Supreme Court, appears as follows: “[W]e set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. . . . If so, we then ask, ‘[w]hat else is there in the claims before us?’ . . . To answer that question, we consider the elements of each claim both individually and ‘as an ordered combination’ to determine whether the additional elements ‘transform the nature of the claim’ into a patent-eligible application. . . . We have described step two of this analysis as a search for an ‘inventive concept’ — *i.e.*, an element or combination of elements that is ‘sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.’” *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S. Ct. 2347, 2355 (2014)

² The question presented in the *Sequenom* petition was: “Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery?” See <https://www.scotusblog.com/wp-content/uploads/2016/04/Sequenom-Cert-Petition.pdf>.

³ See the complete listing at <https://www.scotusblog.com/case-files/cases/sequenom-inc-v-ariosa-diagnostics-inc/>.

I served as counsel for one⁴ of these 20-some amici and urged the Court to address the following question:

Given the current explicit statutory limitations on patenting in the Patent Act—and the proper interpretation of those limitations—should the Court’s judicially imposed implicit exception to subject matter considered to be eligible for patenting be abrogated, such that patentability and patent validity are to be determined solely under such explicit statutory provisions?”

If the Court had taken up the question I posed, there would have been overwhelming arguments for the Court to consider that, I believe, should have compelled the Court to abrogate its troublesome precedents. Given, however, that the Supreme Court denied certiorari in *Sequenom*—and given that today the Court is highly unlikely to grant certiorari for the purpose of abrogating its “implicit exception” holdings—Congress should now act to do so.

I strongly support the legislation proposed on May 22⁵ to couple the legislative abrogation of the Supreme Court’s “implicit exception” precedents with a more complete codification of the principle that patents should only be available for practically useful applications of any laws, phenomena, or other ideas to which an invention relates or on which an invention is based. *Patents should only be for inventions exhibiting a specific and substantial usefulness applied to an area of human endeavor in a field of technology.* The patent statute should explicitly say as much.

Finally, with the “explicit exception” doctrine abrogated, the principle that all patent claims must be fully supported by a sufficient disclosure—commensurate with the scope of protection being sought—will need to play a more prominent and consistent role in limiting available patent protection. I, therefore, urge support for the expansion of the remedial provisions in section 112(f) of the patent statute, as proposed on May 22.

The proposed expansion of § 112(f)’s remedial effects—to apply to all claims with functionally defined elements—will assure that patent claims that might otherwise be construed broadly to cover a function the invention is to perform will be properly titrated down to only those practical applications of the function specified in the claim actually described in the patent’s specification.

⁴ See Amicus Brief of Eli Lilly and Company, *et al.*, available at <https://www.scotusblog.com/wp-content/uploads/2016/04/15-1182-Amicus-Brief-of-Eli-Lilly-et-al..pdf>.

⁵ See *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act*, May 22, 2019, available at <https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act>.

If this can be done, some otherwise invalidly broad patent claims could be found sufficiently disclosed and valid—and anyone reading a patent will be able to more clearly identify the limits on what the patent protects.

With so much at stake, Congress should find a consensus to abrogate the current judge-made law and then articulate with clarity how the statutory law will otherwise limit patenting to what the inventor was able to fully describe and fully enable in seeking to patent.

Background and a Call for Legislative Action

Based on all my experience over more than four decades, I have never been involved with an issue of patent law and practice that is as troubled as the issue of the rules under which subject matter that can qualify as being eligible for protection through a patent. Part of the troubled nature of this area of the patent law today is that court decisions consistently muddle three distinct principles that should operate independently, yet in concert, to appropriately restrict the rights available to inventors through the grant of a patent. These are the principles of *tangibility*, *proportionality* and *inventiveness*—distinct principles that the Supreme Court has now distressingly comingled in an intellectually indefensible manner.

In a patent system that can now boast a 230-year heritage, having such a fundamental issue of patent law so fundamentally troubled is nothing less than a travesty. Allowing such an unacceptable state of affairs with our patent law to continue much longer, would be nothing less than inexcusable.

A patent system that has been in operation for nearly 230 years should have resolved by now what it means for subject matter to be either eligible or ineligible for patenting. While the concept that some subject matter should be eligible for patent protection—and other subject matter should not be—is simple enough to state, the legal principles now mandated to make this eligibility determination have an aspect of arbitrariness in their application that is entirely unacceptable. This arbitrariness compromises the ability of the patent system to operate with the attributes of a property rights system, chief among which is having clear rules as to the nature of the property that is eligible to be protected.

The hope and promise of the three hearings scheduled by this Subcommittee is that they can jump-start a legislative process that might rapidly come to fruition. That process is now postured to bring together the intellect and experience needed to unravel the overly complicated fabric of the current law on patent eligibility. It carries the hope and prospect of knitting together some fundamentally simpler approaches to defining the parameters that should limit the reach of the patent law in protecting the discoveries of inventors—whether based upon eligibility, disclosure-sufficiency, or inventiveness principles.

For my part, I am here today largely to urge that the bipartisan, bicameral proposal circulated by the Chair and Ranking Member of this Subcommittee and Representatives Collins, Johnson, and Stivers on May 22, 2019⁶ be used as the framework for a legislative remediation of the law on patent eligibility. In my view, the May 22 Bipartisan, Bicameral Proposal has enormous merit. It deserves the support of a wide spectrum of constituencies that are impacted by the operation of the patent system. In addition to offering unqualified support for the proposal, I offer a set of clarifying modifications to the proposal as originally presented. I believe a modest set of clarifying changes merit discussion and possible adoption as the legislative process moves forward in search of the consensus that will be needed for its enactment.

Patent-Limiting Principles of Tangibility, Inventiveness, and Proportionality

For a patent system to work well, the protection afforded under a patent needs to be carefully, thoughtfully, and comprehensively limited. To have the attributes of a property rights system, the definition of the limitations on patenting would ideally be addressed through legal principles that are *transparent, objective, predictable, and simple* in their application.

If obliged to boil a patent system down a set of essential principles that ought to define policy-driven limits on protection through a patent, they would be just three: *tangibility, proportionality, and inventiveness*. I would like to begin an explanation of my support for the May 22 Bipartisan, Bicameral Proposal by offering some perspectives on these three defining elements that collectively ought to limit available patent protection in a principled manner, consistent with the patent law’s constitutional purpose.

To this end, the comments I provide in what follows will attempt to explain how, by conflating these three principles, the law on subject matter eligibility for patenting has become a muddled mess. Given my view that the muddling has now passed the point of no return, the discussion below will further articulate why I support *abrogation*—producing a clean slate with respect to the Supreme Court’s interventions—coupled with a statutory *clarification* of the principles that ought to limit the nature and breadth of protection that an inventor ought to have a right to secure.

The Principle of Tangibility

First off, patents have never been able to protect mere ideas or other concepts—whether those ideas or concepts might be labeled as a “law” or a “phenomenon” or some other form of intellectual abstraction, *i.e.*, an “abstract idea.” A broad consensus has always existed that patents serve to protect the novel, useful, and non-obvious *embodiments* of such intellectual concepts—and should not afford dominion over any idea of any type.

Constitutionally, patents exist to advance progress in useful arts. This is a constitutional imperative that, at its core, must require—at least implicitly—that patent

⁶ Referenced in this testimony as the “May 22 Bipartisan, Bicameral Proposal.”

cover only *useful applications* of any concept on which a new discovery is based. Put another way, patents need to be most fundamentally limited to things that are *tangible*—the things that embody the invention—whether that tangibility takes the form of a *process, machine, manufacture, or composition of matter*. These tangible things advance useful arts when they contribute some *practical value* to an area of *human endeavor* in some *field of technology*.

If a consensus can be reached on what the principle of *tangibility* must necessarily entail, then the indisputable components of the principle of *tangibility* ought to be fully codified into the patent statute—under the notion that reading the statute ought to provide the very best clue of what the law actually mandates in order to secure a valid property right. The express provisions of 35 U.S.C. § 101 should, in a nutshell, more fully reflect all essential aspects of this principle of *tangibility*—and do so more completely than they do today.

One reason for putting more meat on the current statutory bones laying out the principle of *tangibility* is that the express provisions of § 101 have remained unchanged since their enactment nearly 70 years ago—as part of the 1952 Patent Act.⁷ As technology has grown more complex and new fields of technology have emerged (*e.g.*, genetic engineering), it has become more challenging than ever to apply ancient, bare-bones concepts of patent law to entirely new areas of human endeavor.

Thus, one objective of any effort to abrogate the Supreme Court’s “implicit exception” jurisprudence should be to assure that § 101 fully reflects that patent-eligible inventions are limited to those practically useful applications, *i.e.*, those processes, machines, manufactures, and compositions of matter, contributing practically (*i.e.*, specifically and substantially) to an area of human endeavor in a field of technology. The challenge with any such initiative will lie in the quest for a sufficient consensus to allow § 101 itself to be at last cracked open for amendment for the first time in generations.

The Principle of Proportionality

The principle of *proportionality* plays an equally essential role in limiting the subject matter that can be patented. For at least some inventors, it can be the patent system’s the biggest bugaboo because it serves to strictly confine the scope of claims that can be patented, based on how fully and extensively the specification of the patent has described the invention.

It is entirely understandable that inventors seek patents claiming their inventions expansively. For example, it is not unknown that inventors may pursue patent protection over the *concepts underlying their inventions*, not merely the tangible embodiments that they describe for implementing those concepts in the specifications of their patents. The first inventor to achieve particular result may assert the right to cover all means later-discovered for achieving that result. Even if such a motivation by an inventor may be entirely understandable, designing a patent system that would facilitate awarding

⁷ Patent Act of 1952, Pub. L. No. 93-593, 66 Stat. 792 (July 19, 1952).

inventors such preemptive patent rights is all but impossible to justify on policy grounds *if the constitutional reference to promoting progress in useful arts* serves to constrain the manner in which Congress is permitted to design a patent system.

Perhaps the historically most notorious example of this type of “over-patenting” by an inventor is found in the telegraph-related patent of Samuel Morse. In *O’Reilly v. Morse*, 56 U.S. 62 (1854), the Court invalidated the eighth claim of the Morse patent. The invalidated claim had defined the Morse invention as the application of a natural phenomenon, specifically, “the use of the motive power of ... electro-magnetism, however developed, for marking or printing intelligible characters, signs, or letters, at any distances.” 56 U.S. at 112.

This particular claim of the patent failed to further identify what the invention was—other than the result to be achieved. No one disputed that Samuel Morse was the first inventor to have produced a machine capable of achieving the claimed result. Such a claim, however, was found to be unpatentable under the *proportionality* principle. The broad (preemptive) scope of the eighth claim of Morse was not *proportionate* to what the Morse patent had described in the way of actual machines to produce the result: “And if [the eighth claim] stands, it must stand simply on the ground that the broad terms above-mentioned were a sufficient description In our judgment the act of Congress cannot be so construed.” 56 U.S. at 120.

The Supreme Court held such a claim could not possibly be valid under the statutory test then requiring a sufficient description—the precursor to 35 U.S.C. § 112(a) in the present patent statute—because the claim sought to protect all means of achieving a functionally defined end. No description in a patent specification could ever be capable of doing so and such functionally defined inventions are inherently incapable of satisfying a § 112(a) disclosure-sufficiency standard.

The Morse patent is not the only example of where the Supreme Court sought to impose a rule of *proportionality* with respect to the patent specification’s disclosure-sufficiency in the face of what the Court viewed as “over-patenting” relative to the invention actually disclosed. The 20th century incarnation of the Supreme Court’s *O’Reilly v. Morse* disclosure-insufficiency jurisprudence appears in its decision in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 13 (1946).

In *Halliburton*, the claims of a patent issued to Walker contained a crucial element defining that element only in terms of the function to be performed by that element, “means associated with [a] pressure responsive device for tuning ...” in order to accent certain waves. Walker’s disclosure of the means for doing so was limited to an “acoustical resonator.” As with the Morse claim, the Walker claim was held invalid under a § 112(a)-disclosure-insufficiency finding: “Had Walker accurately *described the machine he claims to have invented* [in the claims at issue], he would have had no such broad rights to bar the use of all devices now or hereafter known which could accent waves. For had he accurately described the resonator ..., and sued for infringement, charging the use of something else used in combination to accent the waves, the alleged

infringer could have prevailed if the substituted device (1) performed a substantially different function; (2) was not known at the date of Walker’s patent as a proper substitute for the resonator; or (3) had been actually invented after the date of the patent. ...Certainly, if we are to be consistent with [the then applicable disclosure-sufficiency statute], a patentee *cannot obtain greater coverage by failing to describe his invention than by describing it as the statute commands.*” [Emphasis supplied.]

Congress responded to the 1946 *Halliburton* holding in the 1952 Patent Act with the enactment of what is now 35 U.S.C. § 112(f).⁸ As noted above, another subsection of § 112—§ 112(a)⁹—now codifies the statutory disclosure-sufficiency standard that was applied in *Halliburton* to invalidate the Walker claim.

The new § 112(f) was designed to serve—and has served—a profoundly remedial purpose. Had the new § 112(f) statute been in place when the Walker patent was issued, the limited scope of the Walker claim, as construed under § 112(f), should have mooted the Supreme Court’s invalidity holding for the Walker claims. The crucial claim element in the Walker patent would have been limited to an “acoustical resonator” and its equivalent structures. The disclosure-sufficiency standard under § 112(a) should have been satisfied by the very description of the acoustical resonator that limited the claims pursuant to § 112(f).

Under § 112(f) as enacted under the 1952 Patent Act, *all claim elements of every multi-element (“combination”) claim*—not just the crucial claim elements—that set out the element as a specified function can be subject to § 112(f)’s limitation. If § 112(f) applies to the element, it must then be interpreted to cover only the corresponding structure, material, or acts described in the specification of the patent and their equivalents.¹⁰ Limiting the claim coverage under the claim, § 112(f), as that subsection now exists in the current patent law, can prevent a claim from being found invalid as insufficiently disclosed—because the claim would be confined in scope to the devices actually described in the patent specification for performing the function specified in the claim element. It is for this reason that existing § 112(f)—to the extent it can be applied to a claim element—is such a powerfully remedial statute mooting the basis for the Supreme Court’s invalidation of a Walker-type functionally defined claim.

The Federal Circuit would eventually (and, I believe, perplexingly) interpret this remedial statute in a constraining manner, by presumptively limiting its remedial effects

⁸ As originally enacted, § 112(f) was the third undesignated paragraph of § 112, before being demoted to the sixth paragraph in 1975. See the Patent Cooperation Treaty Act, Public Law 94-131, sec. 7, 89 Stat. 691, reenacting the second paragraph of § 112 as three distinct paragraphs to address multiple claim dependencies, effective November 14, 1975. The designation of the paragraphs as subsections was done as part of the Leahy-Smith America Invents Act (herein the “AIA”), Public Law 112-29, sec. 4(c), 125 Stat. 284, and became effective on September 16, 2012.

⁹ 35 U.S.C. § 112(a) was the first undesignated paragraph of § 112 until the AIA became law in 2012.

¹⁰ “An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.”

to a claim where the actual words “means for” or “step for” appear in the claim element. If (under existing Federal Circuit precedent) these “magic words” are absent from a claim element written otherwise only in terms of “performing a specified function without the recital of structure, material, or acts in support thereof,” the § 112(f) applicability presumption then flips. Section 112(f) becomes—in the absence of such “magic words”—presumptively inapplicable to the claim. When § 112(f) is inapplicable—and its remedial effects are unavailable—the claim is exposed to the full force and effect of the Supreme Court’s holding in *Halliburton*, potentially invalidating the claim.

The current form of the Federal Circuit’s dueling presumptions of applicability/inapplicability are explained by the court in *Williamson v. Citrix Online, LLC*, 792 F. 3d 1339, 1349 (Fed. Cir. 2015).¹¹ As a remedial provision, nothing in the legislative history of the 1952 Patent Act would have precluded the Federal Circuit from presumptively applying § 112(f) to every functionally defined element in a multi-element claim, irrespective of the presence of the actual words “means for” or “step for” in the claim—just as nothing would now prevent Congress for doing likewise as a legislative correction of Federal Circuit jurisprudence.

With respect to the policy underlying both the disclosure-sufficiency standard under § 112(a) and its remedial counterpart under § 112(f), it is today quite difficult to find any reasoned commentary to suggest that patent rights should extend to all means for achieving a functionally defined end such that the text of either subsection (a) or (f) of § 112 requires some rethinking or even recalibration. A property-rights system offering functionally defined protection would be utterly unworkable in practice—particularly if all 300,000 U.S. patents issued each year were to define the scope of protection only through a function to be performed, a result to be achieved, a property to be exhibited, or a mechanism by which the invention acted. Such patents, by effectively claiming ideas or concepts, would create unacceptable uncertainties as to what specific subject matter was being protected—most troublingly, what later-invented discoveries would fall within the patented “concept” and thus infringe such a conceptually defined patent.

Applying the principle of *proportionality*, however, the higher the quantity and quality of what is disclosed in the patent specification with respect to what the invention *is*—rather than what the inventions *does*—the greater the scope of protection the inventor should be entitled to receive. It should hardly be a shocking notion, much less an unfair one, that the less an inventor is able to explain in the patent’s specification, the more

¹¹ 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.’” As a remedial provision, a more normal construction of this statute might have been that § 112(f) applies to any claim element that fails to recite sufficiently definite structure, *i.e.*, recites what can be properly construed as a *function*, but without limiting the claim element by reciting sufficient structure for performing that stated function.

narrowly confined the inventor’s claims must be in order to be found valid—and the less the patent merits protecting.

Under the 1952 Patent Act, as noted above, the principle of *proportionality* is not only entirely statutory, but the earlier Supreme Court precedents in *O’Reilly v. Morse* and *Halliburton v. Walker* have remained the bedrock for construing § 112(a). The standard under § 112(a) is clear and brief: “The specification [of a patent] shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...”

The required disclosure under § 112(a) has two essential elements. The first element is to provide a description of what the invention *is* in terms other than what the invention *does*—whether the *what it does* is a function the invention is to perform, a result the invention is to achieve, a property the invention must exhibit, or a mechanism through which the invention is to act. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc). The second element is to provide information on applying the invention in sufficient detail so the full scope of the subject matter claimed can be put into practical application without an inordinate amount of effort—without “undue experimentation.” *In re Wands*, 858 F.2d 731, 737 (Fed.Cir.1988), “The term ‘undue experimentation’ does not appear in the statute, but it is well established that this type of ‘enablement’ requires that the specification teach those in the art to make and use the invention without undue experimentation.”

Thus, in a patent system where 35 U.S.C. § 112 does its job properly, the principle of proportionality should be entirely vindicated through purely statutory provisions. Under § 112(a), a strict standard is set for the description that can be sufficient to support a valid patent claim. Then, under § 112(f), a patent claim that is no more than an effort to ensnare concept on which the invention is based or operates—through a “specified function without the recital of structure, material, or acts in support thereof”—must be cut back such that the coverage under the claim is limited to “the corresponding structure, material, or acts described in the specification and equivalents thereof.”

The Principle of Inventiveness

Finally, the principle of *inventiveness* also operates—as it should—to profoundly restrict the subject matter that can be patented. It is self-evidently no less important than the principles of *tangibility* and *proportionality*. One challenge with the emergence of the *Mayo/Alice* two-part test, is that the principle of inventiveness has been confusingly intertwined with the concept of *eligibility*.

Most patent cognoscenti would contend that the principle that only *inventive* subject matter should qualify for a patent can—and should—be entirely distinct from any principles of law used to assess *tangibility* or *proportionality*. It should not be necessary, therefore, for the assessment of subject matter eligibility—or the proportionality of what

is being claimed—to have a connection to the principle that only inventive subject matter can be patented. There is no logic to connecting the question of whether what is claimed is something *tangible* and *proportionate* to whether that subject matter can be regarded as sufficiently *inventive* to merit patenting.

The core of the *inventiveness* principle is simple to state. *Patents should not afford protection for that which the public already has the benefit—or for what differs in only trivial ways from that which the public already has already been able to benefit.*

As Congress thinks through whether abrogating “implicit exception” jurisprudence requires some statutory invention to impose a different or higher form of inventiveness to a post-abrogation patent statute, it is useful to reflect not only on how long, but on how well the current patent statute has been able to address whether a patent claim represents a sufficient inventive contribution to merit the scope of protection being sought. Under the statutory provision implementing the patent-limiting principle of inventiveness, validly patented subject matter must be not just new—and *not just trivially different*—but it must be *non-obviously different*, from anything theretofore known.

The Supreme Court has set out the core principle for what can be new in *Peters v. Active Mfg. Co.*, 129 US 530, 537 (1889): “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).

Whether what is being claimed by an inventor meets the standard of being sufficiently different (non-obviously different) in order to satisfy the principle of inventiveness has been fully captured through a statutory provision first added to the patent statute in 1952. This provision is found in 35 U.S.C. § 103 and comprehensively captures the principle of inventiveness: “A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in [the prior art], if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.”

It is difficult to imagine that more in the way of a statutory standard for inventiveness is needed than has been imposed on inventors under § 103 for nearly 70 years. With such a comprehensive requirement for non-obviousness in the patent statute, I would submit that there is no possible justification for a different—or even merely duplicate—provision in the patent law that would refuse a patent as insufficiently inventive on subject matter eligibility grounds.

Abrogating the “implicit exception” should not change this outcome. With or without the two-part test, it is impossible to grasp why any claimed invention found to be non-obvious under § 103 should be denied a patent because lack of an “inventive

concept” must deny patent eligibility to what is non-obviously (and, therefore, inventively) different from all that has come before.

The Failed Supreme Court “Experiment” to Conflate Tangibility With Inventiveness and Proportionality Using a Now-Infamous “Two-Part Test.”

In recent years, the Supreme Court has embarked on what might in hindsight be characterized as an “experiment” on the patent system to determine if these three distinct, but complementary, principles of *tangibility*, *proportionality*, and *inventiveness* might be melded into a single analysis. Through several holdings— *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), *Mayo Collaborative v. Prometheus Labs.*, 132 S. Ct. 1289 (2012), *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), and *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S. Ct. 2347 (2014)—the Court has developed its “implicit exception” jurisprudence that purports to limit the subject matter that might otherwise be eligible for patenting under 35 U.S.C. § 101.

As briefly noted above, the gist of the “implicit exception analysis” is found in what today is often termed the “*Mayo-Alice* two-part test.” Under this test for subject matter eligibility, a determination is made if the claimed invention is *directed to* a natural law or phenomenon or other abstract idea and, if so, whether the claim includes significantly more in way of some *inventive concept*. The first element of this “implicit exception” analysis effectively imposes a *proportionality/disclosure-sufficiency* filter (independent from and in addition to the *proportionality* principle codified through § 112(a)) and the second element imposes an *inventiveness/non-obviousness* filter (independent from and in addition to the *inventiveness* principle codified in § 103).

Thus, when the explicit requirements in § 101 for *tangibility* are combined with the implicit requirements now imposed by the Supreme Court under the two-part test, the § 101 analysis can effectively swallow—and more than supersede—the need to read farther into the patent statute to determine if a claimed invention can be validly patented.

The Supreme Court’s experimentation with this “implicit exception” might have constituted more than judicial alchemy if its two-part test had been prone to operational soundness in its real-world application. However, each part of the two-part test, applied to the real-world of examining patent applications and resolving patent validity in infringement actions, is highly problematic.

Both the filters imposed under the *Mayo/Alice* analysis have proven inferior to the statutory standards that they appear either to roughly duplicate or unwisely supersede. The inferiority comes in part from the difficulty of applying these judge-made filters in any predictable manner. As a result, whether a claimed invention is or is not “patent eligible” today is fraught with an unacceptable degree of uncertainty.

As briefly mentioned above, I would assert that the test mandates a hopelessly vague inquiry that, indeed, would raise fatal constitutional issues were Congress to simply codify the *Mayo/Alice* two-part test as statutory law. In other contexts, the

Supreme Court has been clear that vague/arbitrary statutory standards make bad law: “We conclude that the statute as it has been construed is unconstitutionally vague within the meaning of the Due Process Clause of the Fourteenth Amendment by failing to clarify what is contemplated....” *Kolender v. Lawson*, 461 US 352, 353-354 (1983). “A vague law impermissibly delegates basic policy matters to ... judges, and juries for resolution on an *ad hoc* and subjective basis, with the attendant dangers of arbitrary and discriminatory applications.” *Grayned v. City of Rockford*, 408 US 104, 108-109 (1972).

As the two-part test operates *today*, it permits one learned judge to draft a cogent opinion that could invalidate a seemingly innocuous claim as patent ineligible—and a second learned jurist to draft a counter opinion analyzing the same claim to persuasively demonstrate the folly of the *Mayo/Alice* analysis invalidating the claim. See *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, 915 F.3d 743 (Fed. Cir. 2019). According to Judge Lourie: “Because claims ... recite only a natural law together with conventional steps to detect that law, they are ineligible under § 101. For the foregoing reasons, we affirm the judgment of the district court.” 915 F.3d at 757. In dissent, Judge Newman sits on the opposite pole: “Applying the *Mayo/Alice* protocol of two-step claim analysis, claims ... patent are patent-eligible under Step 1, for this method of diagnosing ... is not a law of nature, but a man-made chemical-biomedical procedure. Claims ... recite a combination of technologic steps, all of which are limitations to the claims and cannot be disregarded whether for patentability or patent-eligibility or infringement.” 915 F.3d at 762.

The problematic aspects of using the *Mayo/Alice* two-part test as a tangibility-inventiveness-proportionality-all-in-one-conflating determination lies in the temptation of a court to stretch the *Mayo/Alice* doctrine in various ways to assure it covers a claim that—on its face—does not appear patentable under any one of the three patent-limiting principles, thereby creating a quintessentially bad-cases-make-bad-law precedent that thereafter may be applied to invalidate claims for which subject matter eligibility otherwise might have been beyond serious question. See *Roche Molecular Systems, Inc. v. Cepheid*, 905 F. 3d 1363, 1375 (Fed. Cir. 2018), Judge O’Malley, concurring opinion, “I write separately to express my belief that we should revisit our [earlier] holding in *BRCA1* at least with respect to the primer claims. Specifically, I believe that our holding there was unduly broad for two reasons... .”

The carnage the two-part test inflicts on subject matter eligibility has can be seen in three other Federal Circuit opinions that are particularly worthy of note. See, respectively, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), J. Linn (dissenting in part and concurring in part); *Smart Systems Innovations v. Chicago Transit Auth.*, 873 F. 3d 1364 (Fed. Cir. 2017), J. Linn (dissenting); and *Interval Licensing LLC v. AOL, Inc.*, 896 F. 3d 1335 (Fed. Cir. 2018), J. Plager (dissenting) [Emphasis supplied]:

- “I join the court’s opinion invalidating the claims of the [Sequenom] patent *only because I am bound by the sweeping language of the test* set out in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* In my view, the

breadth of the second part of the test was unnecessary to the decision reached in *Mayo*. *This case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain.*” 788 F.3d at 1380.

- “Because the majority’s determination with respect to the representative claims ... is consistent with past decisions finding ineligibility, I concur with that part of its decision, *not because the inventions covered by the claims do not deserve patent protection but because I am bound by precedent to reach that conclusion.*” 873 F.3d at 1376.
- “Today we are called upon to decide the fate of some inventor’s efforts, whether for good or ill, on the basis of criteria [under the *Mayo/Alice* two-part test] that provide no insight into whether the invention is good or ill. Given the current state of the law regarding what inventions are patent eligible, and in light of our governing precedents, I concur in the carefully reasoned opinion by my colleagues in the majority, *even though the state of the law is such as to give little confidence that the outcome is necessarily correct.* The law, as I shall explain, renders it *near impossible to know with any certainty whether the invention is or is not patent eligible.* Accordingly, I also respectfully dissent from our court’s continued application of this *incoherent body of doctrine.*” 896 F.3d at 1348.

However heroic the Supreme Court’s efforts may have been to find a trinity doctrine to cover the waterfront of *tangibility, inventiveness, and proportionality* in a three-in-one “implicit exception,” by any measure—if an experiment—it can now be adjudicated to be a failed one. The very utterness of that failure makes prompt congressional intervention an imperative.

The Case for Abrogation of any “Implicit Exception” to § 101-Eligible Subject Matter

Given that the patent statute has longstanding, fully effective, and statutorily explicit standards for *proportionality* and *inventiveness* in Title 35 itself, the Supreme Court’s non-statutory, judicially imposed add-ons to the statute can hardly be thought of as essential for any policy reason. As outlined above, *the statutory provisions they either duplicate or supersede otherwise suffice magnificently to confine patent protection to the extent as required for the patent system to operate in consonance with its constitutional purpose.*

Congress would be hard pressed to find that statutory provisions of § 103 and § 112—stringently demanding inventiveness and proportionality—fail to confine available patent protection to constitutionally dictated limitations. Once Congress is satisfied that the rigorous application of the § 103 non-obviousness requirement and the § 112(a) disclosure-sufficiency requirement appropriately bound the patent system within constitutional guardrails, abrogation of the Supreme Court’s implicit exception forms a self-evident solution for the problems the Court has created.

Sound evidence also points to the “implicit exception” doctrine’s inconsistency with the effective operation of a property rights system—in which predictability and

certainty with respect to the nature and extent of the valid property rights is key to the ability to invest in the development and commercialization of new technology. It is that ability for patents to serve as such an investment incentive that permits the patent laws to serve their constitutional purpose of the patent laws to promote progress in useful arts.

As noted above, lower court judges forced to implement the Supreme Court precedents have already spoken in their opinions about the difficulties with the existing state of the law. The holdings in the cases discussed above—all by themselves—should be all the evidence that Congress would need to conclude that the patent law must be altered through a statutory course correction that could be as limited in scope is simply abrogating an unnecessary conflation of inventiveness and proportionality principles into a patent eligibility analysis.

Once Congress finds that the application in practice of the “implicit exception” doctrine frustrates the discharge of the patent system’s constitutional purpose, Congress can and should legislatively overrule the “implicit exception” jurisprudence.

Thus, if these hearings do nothing more, they will hopefully provide a sound and compelling record that supports abrogation of the implicit exception jurisprudence in favor of reliance on statutory standards found in 35 U.S.C. § 101, § 102/§ 103, and § 112(a) to assure that patents can neither preempt access to the basic tool of scientific or technological work nor afford protection over any natural law or phenomenon or other abstract idea.¹²

The only additional diligence that would be appropriate, should Congress proceed with the abrogation of the implicit exception, would be a determination of whether any additional changes to the patent statute that might be appropriate to clarify the manner in which § 101, § 102, § 103, and § 112(a) suffice to impose the necessary and otherwise appropriate proportionality/inventiveness limitations to constrain patentable subject matter.

¹² As set forth in Appendix A, the abrogation can be efficiently accomplished through enactment of a “rule of construction. The proposed text would both abrogate and provide a directive that patents must be issued and regarded as valid as though § 101 contains no “implicit exception,” as follows:

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.

Abrogate and Augment: Bolster Statutory Tangibility and Proportionality Principles

More Fulsome Codification of a “Practically Useful Application”

In addition to legislative abrogation, there are additional changes to the patent statute that would be prudent concomitants to abrogation. These are the changes that were outlined in the May 22 Bipartisan, Bicameral Proposal.

The first such statutory intervention would address more completely in the statute the issue of tangibility—the principle that patents are for practically useful applications of the laws, phenomena, or other ideas on which an invention might be based or be found to operate. Congress might do so through a more comprehensive codification the manner in which the courts, including the Supreme Court, have implemented the statutory requirement for “utility” under § 101.

Congress first used the term “useful” that appears in § 101 of the 1952 Patent Act in connection with the required *tangibility* of the subject matter that might be eligible for patenting in 1790, when Congress permitted patents to issue for “any useful art, manufacture, engine, machine, or device, or any improvement therein... .”¹³ The ancient lineage of this term suggests its essential constitutional context. Under the Constitution it is only “useful arts” that patent law must serve to advance.

Sound scholarship would suggest that granting patents on subject matter that is not sufficiently useful or not sufficiently connected to a “useful art,” would fall outside the authorization given Congress under the Constitution to afford “exclusive rights” to inventors. While this principle is especially applicable in the case for so-called “method” claims defining a *process* containing one or more specified *steps* describing separate *acts* to be undertaken, it applies to patents of all types.

Nothing in the U.S. Constitution, for example, would appear to permit, much less encourage, the issuance of a patent for novel method for playing hopscotch.¹⁴ However novel and non-obvious such a method might be—and however proportionate the claims are to the disclosure of the method in the patent specification—§ 101 of the patent statute ought to provide a clear basis for clarifying that the United States has a hopscotch-free patent system.¹⁵

¹³ Patent Act of 1790, Ch. 7, 1 Stat. 109-112.

¹⁴ “[T]he importance of the [constitutional] word ‘useful’ is to enable patentability for processes and methods..., but only with respect to their contribution to a patentable ‘trade.’ ... Webster ... defined a ‘trade’ as being ‘distinguished from the liberal arts and learned professions, and from agriculture.’” Brief of Amicus Tony Dutra in Support of Respondents, *Alice Corp. v. CLS Bank* (App. No. 13-298) at p. 8, at http://www.americanbar.org/content/dam/aba/publications/supreme_court_preview/briefs-v3/13-298_resp_amcu_td.authcheckdam.pdf.

¹⁵ The same principle ought to apply to improved methods for swinging on a swing hung from a tree branch. 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

In this regard, the *usefulness* that the courts have found to be required is a *specific and substantial* usefulness. An accepted, shorthand way of expressing the *specific and substantial* usefulness required is the necessity for a *practical utility*. Moreover, the notion of practicality is a contextual one—it is practicality with respect to useful arts.

Any attempt to list exhaustively the useful arts would necessarily need to reflect the emergence of new technologies and the recession of old ones—LED lamp-making now predominates over the candlemaker’s art. For shorthand purposes, useful arts can be thought of as synonymous with a field of technology. As such, a field of technology would readily distinguish useful arts from the *liberal arts*.

While it has been said that patents ought to be available for “anything under the sun made by man,” the Constitution would seem to be a tad more restrictive in the reach of the patent laws that Congress is given the power to enact. The constitutional remit for Congress is to enact progress-promoting laws as applied to an area of *human endeavor in a field of technology*. Those progress-promoting laws would not protect “*anything*,” but rather those *tangible* things (process, machine, manufacture, or composition of matter) that were *specifically and substantially useful when applied to an area of human endeavor in a field of technology*.

Thus, part of the exercise of abrogation of the Supreme Court’s “implicit exception” jurisprudence might be to further codify in § 101 itself both the constitutional and existing judicial constraints that surround the requirement that a claimed invention be “useful.” This would include greater specificity as to the quantum of utility (specific and substantial, *i.e.*, practical) and the necessity that “usefulness” apply to an area of human endeavor in a field of technology (*i.e.*, amount to a practically useful application).

To this end, it would be a constructive exercise, as the May 22 Bipartisan, Bicameral Proposal has undertaken, to define in the patent statute itself precisely what it means for a claimed invention to be *practically useful*. To this end, I would urge the subcommittee to consider the following change to the language proposed in the May 22 Bipartisan, Bicameral Proposal, a change that would provide a definition for the term “practically useful,” rather than the term “useful” presently used in § 101:

(k) The term “practically useful” with respect to a claimed invention means exhibiting a specific and substantial utility as applied to an area of human endeavor within a field of technology.

As set out in more detail in Appendix A to my testimony, this definition more fully captures the holdings of the courts from *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005) and *Brenner v. Manson*, 383 U.S. 519 (1966). Moreover, the definition would clarify in with more contemporary phraseology that “useful arts” represent (and should be

side; and (d) repeating step (c) to create side-to-side swinging motion, relative to the user, that is parallel to the tree branch.”

considered coextensive with) an *area of human endeavor within a field of technology*. Moreover, such a definition would inherently explain that what is practically useful must be *applied* to an area of human endeavor, effectively limiting the reach of the patent system to practically useful applications of any law, phenomenon, or idea to which an invention might relate or on which an invention might be based.

Such a definition would impose inherent limits on the patenting of products as they exist in nature, such as efforts to secure a patent that would provide exclusive rights to a genetic material, such as a human gene. The patent system could offer protection only for practically useful applications of gene-related technology, such as new diagnostic tools and medicinal therapies, but not sanction a patent that would cover a human gene itself. Even then, the *inventiveness* and *proportionality* limitations would further apply to assure that patent rights, even if otherwise available, would not result in exclusivity with respect to a human gene or other product of nature itself.¹⁶

As further elaborated in Appendix A, the above definition for “practically useful” could be best used in an amended § 101 that would make a further substantive change to § 101 enacted through the 1952 Patent Act:

§ 101. ~~Inventions patentable.~~ Right to patent; practical application required; eligible subject matter.

Whoever invents or discovers any ~~new and~~ practically useful process, machine, manufacture, or composition of matter, or any ~~new and~~ practically 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.

As further noted in Appendix A, the amended form of § 101 would provide a new “inventor’s right to patent” provision that would categorically afford an inventor the right to patent an invention once the conditions and requirements under the statute had been met. The intention, in part, would be to underscore that, once the statutory provisions have been met, the inventor must be issued a patent.¹⁷

¹⁶ See also Robert A. Armitage, *Can We Find a Rational, Principled, Expansive, and Politically Palatable Approach to Statutorily Defining Patent Eligibility?*, USPTO Roundtable 2 –Patent Eligibility Contours, available at <https://www.uspto.gov/sites/default/files/documents/RT2%207-1%20Robert%20Armitage.pdf>. This presentation urges adoption of the principles from the so-called *Banbury Statement* (November 11, 2016) on subject matter eligibility for patenting, including: “[c]larify that patent protection shall be available for inventions in all fields of technology and better conform U.S. patent law with internationally accepted norms of patentability. To this end, a number of participants recommended that Congress enact a substitute requirement limiting patent eligibility to technological inventions, *i.e.*, inventions contributing to the technological arts. Such a measure would codify the standard set out in the concurring opinion in *Kappos v. Bilski* and foster greater harmony between U.S. patent law and the patent law in Europe.” See <https://www.uspto.gov/sites/default/files/documents/Updated%20Banbury%20Statement.pdf>.

¹⁷ As noted in Appendix A, the new “right to patent” provision would not apply to the existing grounds on which the USPTO today can refuse to issue a patent, which should be addressed in a rule of construction. The following text is proposed:

Address Proportionality with an Expanded Applicability of § 112(f)

The issue of *proportionality* is more complex and nuanced than the issue of *inventiveness* or the issue of *tangibility*, in part because the disclosure-sufficiency requirement historically has been the dominating force in limiting the scope of available patent protection. The “implicit exception” jurisprudence squarely targets the issue of disproportionality, but as a subject matter eligibility, not a disclosure-insufficiency, issue.

What has resulted in Supreme Court’s “implicit exception” holdings is a doctrinally garbled message on subject matter eligibility, grounding eligibility law in large part on the disclosure-sufficiency requirement that is today set out in § 112(a). Relying on its disclosure-insufficiency holding in *O’Reilly v. Morse*, the Supreme Court now justifies imposing its non-statutory “implicit exception” to what is subject matter eligible for patenting on § 112(a) *proportionality grounds* (*Alice*, 134 S.Ct. at 2354):

“We have long held that [35 U.S.C. § 101] contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable.” *Association for Molecular Pathology v. Myriad Genetics, Inc.* ... (internal quotation marks and brackets omitted). We have interpreted § 101 and its predecessors in light of this exception for more than 150 years. *Bilski* **see also *O’Reilly v. Morse***

We have described the concern that drives this exclusionary principle as one of pre-emption. See, e.g., *Bilski* ... (upholding the patent “would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea”). Laws of nature, natural phenomena, and abstract ideas are “the basic tools of scientific and technological work.” *Myriad* “[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it,” thereby thwarting the primary object of the patent laws. *Mayo* see U.S. Const., Art. I, § 8, cl. 8 (Congress “shall have Power ... To promote the Progress of Science and useful Arts”). We have “repeatedly emphasized this ... concern that patent law not inhibit

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.

further discovery by improperly tying up the future use of these building blocks of human ingenuity. *Mayo*... (citing *Morse* ...).

The twice-cited holding from *O’Reilly v. Morse*, in the course of cementing its “implicit exception” holding in *Alice*, offers Congress a clear pathway to abrogating the “implicit exception” and the *Mayo/Alice* two-part test required to implement it. Congress may constitutionally do so as long as the congressional abrogation makes clear that *O’Reilly v. Morse* (and its 20th century counterpart, *Halliburton v. Walker*) remain controlling law with respect to the *proportionality* principle. In other words, the best pathway to abrogation should be paved with assurances to the Supreme Court that the anti-preemptive effect arising out of the § 112(a) disclosure-sufficiency requirement for patentability remains in full force and effect, in an undiluted manner.

Ideally, therefore, Congress would find some mechanism where it could combine abrogation of the “implicit exception” jurisprudence with a clear reaffirmation of the superseding role that § 112(a) disclosure-sufficiency assessments would take. Doing so would address any possible concern—as the *O’Reilly v. Morse* holding accomplished—“that patent law not inhibit further discovery by improperly tying up the future use of ... building blocks of human ingenuity.” Moreover, it would assure that the Supreme Court would have no possible policy ground on which to find that abrogation of the “implicit exception” jurisprudence would leave the patent law constitutionally defective—for failure to effectively constrain patent rights in a manner essential to assure the law operated to promote, not impede, progress in useful arts.

The May 22 Bipartisan, Bicameral Proposal provides a statutory amendment that should assure that the abrogation of the “implicit exception” jurisprudence of the Supreme Court will not come at the expense of a retreat from the policy imperative that the scope of exclusionary rights under a valid patent must be non-preemptive, *i.e.*, must be *proportionate* to the patent specification’s disclosure of the invention being claimed). The May 22 Bipartisan, Bicameral Proposal contains a provision that I believe is ideally suited as a reaffirmation of the proportionality principle.

This reaffirmation comes in the form of a simple statutory adjustment, through a proposed amendment to 35 U.S.C. § 112(f). The proposed adjustment to § 112(f) makes at least a presumptive change in determining the applicability of § 112(f), but no change to the effect on a claim once § 112(f) is found to be applicable to a claim element. Thus, the consequences of § 112(f) applicability *that have been in place since the original enactment of this subsection of § 112 through the 1952 Patent Act remain entirely unchanged*.¹⁸ What the proposed § 112(f) does is nothing more than to *expand* the

¹⁸ The enactment of § 112(f) in 1952, originally the third paragraph—and later the sixth paragraph—of § 112, was done in response to the Supreme Court’s invalidation of a claim where a crucial claim element of a patent issued to Walker was expressed in functional terms. The claim, thus, stood in clear violation of the proportionality principle. *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 13 (1946), “Had Walker accurately described the machine he claims to have invented, he would have had no such broad rights to bar the use of all devices now or hereafter known which could accent waves. ... [I]f we are to be consistent with [the statutory disclosure-sufficiency requirement], a patentee cannot obtain greater coverage

potential applicability of § 112(f), not the consequences flowing once § 112(f) is applicable to a claim element. Changing § 112(f) in this elegant manner would all but assure that the intended consequences from the amendment would overwhelm any potential for unintended consequences.

This *expand-applicability-but-not-change-consequences* aspect of § 112(f) comes through clearly when the current statute is compared to the proposed amended statute:

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

The May 22 Bipartisan, Bicameral Proposal simply deletes the existing § 112(f) limitation to “combination claims” and its presumptive inapplicability to claims not literally reciting the words “means for” or “step for.”¹⁹ Otherwise, the § 112(f) law from the 1952 Patent Act is entirely undisturbed.²⁰

With the expanded applicability to all claim elements of all types of claims, amended § 112(f) assures that the Morse claim invalidated in *O’Reilly v. Morse* would be construed to cover only the telegraph. Indeed, any effort at clever claims draftsmanship to garner a preemptive scope for a claim would be automatically cut down to the specific embodiments of the invention that the inventor had described in the patent specification.²¹ With amended § 112(f) in the patent statute, *proportionality* would be all

by failing to describe his invention than by describing it as the statute commands.” By limiting the coverage under the claim, § 112(f) mooted the basis for the Supreme Court’s invalidation of the Walker claim.

¹⁹ The Federal Circuit could have, as noted above, simply interpreted § 112(f) in the manner one would have expected such a remedial provision to have been interpreted and made it presumptively applicable to all elements of all combination claims that appeared to be drafted as a specified function without reciting the supporting structures. As noted above, doing so would essentially duplicate the effects of the proposed adjustment to § 112(f) the remove the reference to “means or step for.”

²⁰ Some criticism of the May 22 Bipartisan, Bicameral Proposal has asserted that the amendment to § 112(f) could produce unintended consequences. Such contentions require a close examination that may trigger potential refinements, as needed, to maximize the intended consequences and minimize any possibility for unintended ones. The foremost intended consequence is that claims that otherwise would be invalid under § 112(a), on account of functionally defined elements in a claim rendering the claim insufficiently disclosed, might no longer be subject to invalidation under § 112(a)—because the claim must be construed as limited only to embodiments of the invention that are described in the patent’s specification. For the purpose of heading off potential unintended consequences, Appendix A offers a set of rules of construction designed to assure that the intended consequences of invalidity mitigation vastly outweigh any possibility for mischief.

²¹ The Supreme Court has expressed concern over claim drafting techniques that “would make the determination of patent eligibility ‘depend simply on the draftsman’s art,’ ... thereby eviscerating the rule that ‘[l]aws of nature, natural phenomena, and abstract ideas are not patentable...’” ... This Court has long

but inescapable. *This is exactly the message that Congress should be sending to the courts as the implicit exception is abrogated.*

Hence, the amended § 112(f) not only serves as what many constituencies might see as a necessary complement to the abrogation of the “implicit exception” to subject matter eligibility, but it forms what should be an optimal complement to abrogation of any “implicit exception” to § 101. Amended § 112(f) will require that every discrete element of a claimed invention to be identified and, once identified, to be interpreted in a binary manner, as either a functionally defined element or a structurally defined element.²² This assessment can be done in an entirely presumption-free manner, with the elimination of the words “means or step for performing a” from § 112(f).

Hence, the sole task demanded under amended § 112(f) would be to undertake a presumption-free construction of each individual claim element as structural or functional, using the well-established claim construction principles.²³

Congress Should Leave the Statutory Inventiveness Standard Untouched

Lastly, if Congress proceeds with the abrogation of any “implicit exception” to subject matter that can be considered eligible for patent protection under 35 U.S.C. § 101, it would be essential for Congress to consider whether the *inventiveness* limitation on the ability to secure a valid patent should in any way be augmented—given abolition of the assessment of whether a claim directed to a law, phenomenon, or idea provides significantly more in the way of an inventive concept. In this regard, the standard for inventiveness under 35 U.S.C. § 103 has been in place for nearly 70 years and, today, offers a *comprehensive* assurance that when a claimed invention is assessed as a whole, it must constitute more than just a trivial contribution over the prior art.

The Supreme Court has exercised oversight of the Federal Circuit’s administration of the statutory requirement for non-obviousness. *KSR Int’l Co. v.*

‘warn[ed] ... against’ interpreting § 101 ‘in ways that make patent eligibility depend simply on the draftsman’s art.’” *Alice*, 134 S.Ct. at 2359-2360.

²² To avoid the potential for any unintended consequences, a rule of construction is proposed in Appendix A that would clarify that claim construction under § 112(f) would be the basis for determining if the claimed invention was sufficiently disclosed under § 112(a):

ALL CLAIM LIMITATIONS TO BE CONSIDERED.— 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, including any limitations based on the required claim construction under section 112(f), 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, provided the determination that a claim is sufficiently disclosed under section 112(a) must be made by disregarding equivalents under section 112(f).

²³ *Phillips v. AWH Corp.*, 415 F. 3d 1303 (Fed. Cir. 2005). As an example, the commonly used term “pharmaceutically acceptable salts,” while identifying a result to be achieved, is the name for a well-recognized category of salts, all of which have characterized structures, thus supporting construction of this term as a structural (not functional) one, notwithstanding the category name also identifies its functioning.

Teleflex Inc., 550 U.S. 398 (2007). There is, at present, no hue and cry that the Supreme Court needs to tinker further with the manner in which “common sense” helps to inform the non-obviousness determinations under § 103.²⁴ Since the enactment of the 1952 Patent Act, there have been no serious efforts to impose by statute a more rigorous standard for *inventiveness* than is found under § 103. Indeed, after amending § 103 as enacted under the 1952 Patent Act several times over the decades, Congress through the America Invents Act actually restored § 103 to nearly the same form in which it was originally enacted in 1952.

Given this stability in the statutory framework for assessing *inventiveness* notwithstanding multiple § 103 amendments over the past 70 years—including during the near half-century before the 2010 *Bilski* decision was handed down by the Supreme Court—it would appear that this single, comprehensive *inventiveness* requirement should suffice, even if the “implicit exception” holdings were to be abrogated by Congress. Thus, I would urge the Congress not further tinker with the statutory non-obviousness requirement under 35 U.S.C. § 103 in the course of any effort to abrogate the “implicit exception” to § 101 patent-eligible subject matter.

Effect and Effective Date Provisions Should Apply to All Patents, Absent Opt-Out

The Supreme Court’s development of its “implicit exception” jurisprudence over the past decade has produced unacceptable consequences, as painfully detailed above. Both patent applicants and patent owners should receive the benefit of a remedial action by Congress that would abrogate the implicit exception outright. Thus, the core of any transition provision ought to provide for immediate effect to the abrogation and immediate applicability to all issued U.S. patents, past, present, and future.

Only two exceptions should be provided in a transition provision. One provision should exempt any allegation of infringement in a civil action brought before the date of enactment. The other should allow a patent owner to opt-out of the abrogation—and the companion change to 35 U.S.C. § 112(f). This opt-out would assure that no Takings Clause issue could arise. Obviating any Takings Clause issues is important given that abrogation might resurrect patent eligibility for an otherwise invalid claim, but also might subject an arguably already patent-eligible claim to a § 112(f) claim construction limitation that might constrain its scope once subject to the new law.

Appendix A lays out a suggested text for such a transition provision:

(c) EFFECT AND EFFECTIVE DATE.—The amendments under this Section shall take effect on the date of enactment and shall apply to any patent issued or

²⁴ “*KSR*, however, instructs courts to take a more ‘expansive and flexible approach’ in determining whether a patented invention was obvious at the time it was made. 550 U.S. at 415. In particular, the Court emphasized the role of ‘common sense’: ‘[r]igid preventative rules that deny factfinders recourse to common sense... are neither necessary under our case law nor consistent with it.’ *Id.* at 421.” *Wyers v. Master Lock Co.*, 616 F. 3d 1231, 1238 (Fed. Cir. 2010).

reissued before, on, or after that date, except that this Section and the amendments made herein shall—
(1) not apply to any allegation of infringement in a civil action brought before the date of enactment of this Act.
(2) have no effect with respect to a patent issued before the date of enactment if the patentee provides written notification to the Director, within six months from the date of enactment of this Act, that this Section shall be inapplicable to the patent.

Consideration of Companion Provisions Providing a Complete Legislative Package

As part of the current legislative effort to abrogate the Supreme Court jurisprudence imposing the *Mayo/Alice* two-part test, Congress should consider additional amendments to the patent statute where such further modifications of the patent law would assist in speedy congressional action on the patent-eligibility initiatives found in the May 22 Bipartisan, Bicameral Proposal. Outlined below are two areas where such collateral initiatives might be found.

Essentially Technical Corrections to the Leahy-Smith America Invents Act

While Congress was able to pass H.R. 6621 in the 112th Congress²⁵ to promptly enact a set of technical corrections to the America Invents Act, other needed amendments to the AIA of a technical nature have yet to pass Congress. Two of these amendments are—and should be—entirely without any controversy as to whether they are purely technical in character and should be enacted into law as soon as possible.

A third would be ripe for enactment if, as part of the legislative abrogation of the implicit exception jurisprudence, Congress amends 35 U.S.C. § 101 in the manner discussed above and detailed below in Appendix A.

A fourth removes a vestigial provision from the disclosure requirements for a patent specification that no longer has any bearing on whether a patent is valid and enforceable.

The final amendment would address a recent Supreme Court decision addressing the “prior art” provisions of the AIA that one of the two principal congressional architects and champions of the AIA has explained now works to negate a key AIA-driven reform to the patent laws.²⁶

Such essentially technical corrections include the following:

²⁵ Pub. L. 112-274, 126 Stat. 2456-2459 (Jan. 13, 2013).

²⁶ See Amicus Brief of Congressman Lamar Smith in *Helsinn Healthcare SA v. Teva Pharmaceuticals USA, Inc.*, App. No. 17-1229 (decided Jan. 22, 2019) at https://www.supremecourt.gov/DocketPDF/17/17-1229/40117/20180327102812171_USSC%2017-1229%20Amicus%20Brief%20of%20Lamar%20Smith.pdf.

(1) JOINT INVENTORS.—Sections 102(b)(1)(A), 112(a), and 291(b) of title 35, United States Code, are each amended by striking “or joint inventor” and inserting “or a joint inventor”.

(2) ASSIGNEE FILERS.— Section 119(e)(1) of title 35, United States Code, is amended, in the first sentence, by striking “by an inventor or inventors named” and inserting “that names the inventor or a joint inventor” and section 120 of title 35, United States Code, is amended, in the first sentence, by striking “names an inventor or joint inventor” and inserting “names the inventor or a joint inventor”.

(3) 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)”

(4) MORE APT PREAMBLE.—Section 102(a) of title 35, United States Code, is amended by striking “A person shall be entitled to a patent unless” and insert “A patent for a claimed invention may not be obtained if”.

(5) PRIOR ART CLARIFICATION.—Section 102(a)(1) of title 35, United States Code, is amended by striking “or in public use, on sale,” and section 282 of title 35, United States Code, is amended by inserting 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.”

The first of the amendments proposed above removes a clerical error in the America Invents Act relating to joint inventors. This amendment reflects that the AIA's new definition for the term "inventor" references the so-called "inventive entity" or each of the joint inventors taken collectively in the case of an invention made jointly by two or more individuals. This amendment, as such, is purely grammatical in character.

The second eliminates an error in the America Invents Act in accounting for inventions filed by assignees that name the inventor. This amendment, again purely technical in character, will assure that an inventor cannot forfeit the right to benefit from the filing date of an earlier-filed application for patent solely on the basis of whether the applicant for patent is the inventor or the assignee of the inventor, as the AIA permitted assignee filing of patent applications for the first time in amending 35 U.S.C. § 118.

The third amendment removes vestigial text from title 35 relating to the so-called "best mode" requirement that, subsequent to the enactment of the America Invents Act, no longer serves any remaining function, *i.e.*, no longer has any bearing on the validity or enforceability of an issued patent. While not a purely technical amendment, this amendment is both essentially technical in character and further serves to align U.S. patent law more closely with international norms for the required disclosure in a patent filing.

The fourth amendment provides a new preamble for 35 U.S.C. § 102(a) ("A patent for a claimed invention may not be obtained if...") that provides a missing antecedent for the term "claimed invention" that appears in the text that follows. In addition, this technical change properly aligns the preamble for § 102(a) with that of § 103, and provides a more appropriate preamble given the AIA's amendment of § 102 such that this section of the patent statute no longer recites any "loss of right to patent" provisions, but is instead entirely confined to the issue of novelty and a definition for the term "prior art." As such, this amendment is purely technical in that it has no impact on any issue of patentability or the enforceability of a patent. This amendment becomes particularly ripe if § 101 is amended to recite an explicit "inventor's right to patent" provision, as proposed in Appendix A. In such a circumstance, the existing preamble for § 102 ("A person shall be entitled to a patent unless...") would become confusingly and erroneously duplicative.

The fifth and final amendment overrules the Supreme Court decision in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc.*, App. No. 17-1229, decided January 22, 2019, by removing the words "or in public use, on sale," from 35 U.S.C. § 102(a)(1) so that prior art under this paragraph must be "available to the public," *i.e.*, meet the public availability standard that applied under the law prior to the America Invents Act for inventions "known or use" as set out under pre-AIA § 102(a).²⁷

²⁷"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).

For inventions that are “in public use or on sale,” the fifth amendment further provides a new 35 U.S.C. § 282(d). This new subsection creates an unenforceability defense in situations where such “public use” or “on sale” activities took place *in the United States* more than six years before the effective filing date for a patented invention and the patent has not been terminally disclaimed prior to issuance to prevent its enforcement more than 21 years from the date the claimed invention affected by the use or sale activities was ready for patenting. This new rule on unenforceability operates as a surrogate to invalidating a patent based upon “secret prior art.”²⁸ Given the new unenforceability defense to infringement will act as a replacement for the current “secret prior art” invalidity defense as it now exists following *Helsinn*, the fifth amendment has an essentially technical character. That said, it does confine the defense to inventor-attributable “in public use or on sale” activities and to activities taking place in the United States—thereby better aligning the scope of the unenforceability defense with the scope of the “secret prior art” invalidity defense that applied before the enactment of the AIA.

“Research Use” Exemption—National Academies’ Recommendation

Given the Supreme Court’s expressed view that the 1952 Patent Act has in practice failed to provide adequate assurances that patents could not be used to preempt access to basic tools of scientific and technological work, the Subcommittee should consider the extent to which abrogation of the “implicit exception” might justify moving forward with longstanding legislative proposals providing for infringement-free access to patented inventions when used to promote progress in useful arts through *research* or *experimentation*. In this respect, the Subcommittee might consider whether a new statutory provision should address whether access to patented inventions should be freely available (1) to understand them, (2) improve them, and (3) develop other alternatives to them—through research and experimentation on them.

Were Congress to act to codify an exemption from patent infringement based on research activities, it would not be acting alone or in a vacuum. Other industrialized countries have long had laws permitting so-called “research use” or “experimental use” of patented inventions that could serve as a model for a provision added to the U.S. patent statute.

One proposal for addressing this issue 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*.²⁹ This report could serve as

²⁸ See Amicus Brief of 45 Law Professors in *Helsinn Healthcare SA v. Teva Pharmaceuticals USA, Inc.*, App. No. 17-1229 (decided Jan. 22, 2019), available at http://www.supremecourt.gov/DocketPDF/17/17-1229/66149/20181009122047518_17-1229_Helsinn%20v.%20Teva_bsac.pdf at pp. 11-13. Under the unenforceability defense created under 35 U.S.C. § 282(d), patent claims could become unenforceable, absent a sufficient disclaimer, in three areas in which the pre-AIA law may have rendered such claims invalid under 35 U.S.C. § 102: “(1) ‘noninforming public use’ cases, where an invention is used in public but in a way that is not ascertainable by (and hence arguably not ‘available to’) the public; (2) ‘output of a patented machine or process’ cases, such as *Metallizing Engineering*; and (3) secret, confidential, and nonpublic sales transactions, which under the on sale cases cover the vast majority of on sale events.”

²⁹ This report is available for download at <http://www.nap.edu/catalog/11487.html>.

a model for developing a statutory provision that might align U.S. patent law with that of other industrialized countries. At p. 145, it recommended the following:

Recommendation 10:

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.

The National Academies approach reflected the longstanding and nearly identical view of the American Intellectual Property Law Association:

RESOLVED, that AIPLA supports, in principle, legislation to codify an exemption from infringement under which uses of a claimed invention related to scientific, research, or experimental inquiries are exempted as acts of infringement, and

SPECIFICALLY, the Association supports legislation providing that acts of infringement shall not extend to making or using patented subject matter solely to discern or discover:

- (1) the validity of the patent and the scope of protection afforded under the patent;
- (2) features, properties, inherent characteristics or advantages of the patented subject matter;
- (3) methods of making or using the patented subject matter; or
- (4) alternatives to the patented subject matter, improvements thereto or substitutes therefor.³⁰

This Subcommittee might consider adding a new subsection (j) to 35 U.S.C. § 271 to incorporate these recommendations into law:

Section 271 of title 35, United States Code, is amended by inserting at the end:

“(j) Notwithstanding subsections (a) and (g), it shall not be an act of infringement to make or use a claimed

³⁰ See https://www.aipla.org/docs/default-source/advocacy/past-action-manual---2018-update.pdf?sfvrsn=62759246_0 at pp. 6-7.

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 dis-advantage 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.”

This new subsection (j) 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.

In general, 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.

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, a new subject (j) of § 271 would underscore for the Supreme Court the lack of any continuing policy necessity for its abrogated “implicit exception” jurisprudence.

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.

Conclusions

Congress can best serve the constitutional purpose of the patent system to promote progress in useful arts by abrogating the Supreme Court's "implicit exception" jurisprudence and replacing it with a more complete codification of the principle that patents cannot protect laws, phenomena, or ideas, but only something *tangible*, expressed as a process, machine, manufacture, or composition of matter that is *practically useful as applied to an area of human endeavor in a field of technology*. The task of determining whether the patents issued on such tangible subject matter reflect the proper *proportionality* to the quantity and quality of the disclosure of the invention in the specification of the patent will then rest entirely on a consistent and rigorous application of the disclosure-sufficiency requirement under 35 U.S.C. § 112(a).

To assure that such consistency and rigor in applying the *proportionality principle* is reflected in each of the 300,000 patents issued each year, Congress should expand the remedial provisions of 35 U.S.C. § 112(f) to apply to all claims with functionally defined elements, such that claim construction will invariably assure the principle of proportionality cannot be evaded through any form of clever patent draftsmanship. Congress can do so without unintended consequences by assuring any adjustment to § 112(f) essentially does nothing more than had the judicial construction of existing statute made it presumptively applicable, instead of presumptively inapplicable, to combination claim elements lacking the magic words "means for" or "step for."

At the same time, the expansion of this remedial provision will assure that claims that would otherwise be found invalid for disclosure insufficiency based on their functional character can be found valid once restricted to the embodiments of the invention actually described in the patent's specification. Again, Congress can do so in a manner affording clarity to inventors in the manner § 112(f) will apply to determinations of patentability, particularly the § 112(a) disclosure-sufficiency requirement.

While a legislative package might advance through the committee process with just this combination of abrogation and augmentation relating to the principles of tangibility and proportionality, consideration should be given to adding to the present legislative effort a set of essentially technical corrections to the America Invents Act. Such changes should be made to the extent they are free of any controversy.

Finally, Congress should consider a "research use" exemption from patent infringement. This becomes an issue of particular importance once the "implicit exception" is abrogated legislatively. If this additional element of a legislative package does not complicate the legislative journey ahead with unwanted controversy, it should further assist the Supreme Court to understand the fidelity of this legislative effort to any constitutional limitations imposed upon Congress in enacting the patent laws.

While these hearings may be but the start of the legislative process, they hold the promise of being an auspicious one. Again, my thanks to the Subcommittee for the opportunity to advance the views expressed above.

APPENDIX A: SUGGESTED CLARIFICATIONS TO MAY 2019 PROPOSAL

OVERVIEW

The bipartisan effort to clarify the law on subject matter eligibility for patenting, reported at <https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act>, included the originally proposed language set out below. Technical modifications are suggested to some of the proposed provisions. These technical modifications are intended to retain the substance of the originally proposed text. The rationale for the suggested changes is provided in commentary below.

Section 100 Amendment:

ORIGINALLY PROPOSED:

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

SUGGESTED:

(k) The term “practically useful” with respect to a claimed invention means exhibiting a specific and substantial utility as applied to an area of human endeavor within a field of technology.

COMMENTS:

- (1) The term “practically useful” is suggested to replace “useful” to provide greater fidelity to the case law.
- (2) The definition is proposed to be “with respect to a claimed invention” for greater grammatical clarity.
- (3) The term “specific and substantial” is suggested to replace “specific and practical” on the ground that specificity could be considered as an essential element of the required practicality, affording again potentially greater clarity.
- (4) The term “an area of human endeavor” is suggested to replace “through human intervention” to emphasize the “made by humans” aspect of the work in a field of technology—without using the term “intervention.” (The proposed text does not specify with respect to *what* the human intervention is taking place (*i.e., intervening in what?*)).
- (5) The term “applied to” is incorporated to further clarify the definition effectively imposes a *practical application* standard, again consistent with applicable case law on utility.

The Federal Circuit in *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005), attempted to apply the Supreme Court precedent in *Brenner v. Manson*, 383 U.S. 519 (1966) by holding the required utility under 35 U.S.C. § 101 must *specific, practical, and substantial*, but with the terms “practical” and “substantial” being considered synonymous. 421 F.3d at 1371, including footnote 4, “this court considered the phrase ‘practical utility’ to be synonymous with the phrase ‘substantial utility.’” For the purpose of imposing a *practical application* standard, it may be

preferable to define a new term “*practically useful*” as referencing a “specific and substantial utility,” citing as basis for this legislative language the need to more fully codify the existing requirement from the *Brenner/Fisher* line of cases. In laying out that the utility standard incorporates the notion of a “practical application,” it may be desirable to use the term “applied” in the statute itself, rather than the term “provides.” In a similar vein, it may be desirable to reference the term “practically useful” in terms of a “claimed invention, *i.e.*, “with respect to a claimed invention” for the sake of greater clarity in a new § 100(k). The standard of “human intervention” may also be less clear than “human endeavor” with regard to a “field of technology. Hence, the suggestion is made to consider that the practical application must be “as applied to an area of human endeavor within a field of technology.”

Section 101 Amendment:

ORIGINALLY PROPOSED:

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

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

SUGGESTED:

§ 101 Inventor’s right to patent; practical application required; eligible subject matter.

Whoever invents or discovers any practically useful process, machine, manufacture, or composition of matter, or any useful 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.

Non-Codified Rule of Construction:

(1) ALL CLAIM LIMITATIONS TO BE CONSIDERED.— 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, including any limitations based on the required claim construction under section 112(f), 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, provided the determination that a claim is sufficiently disclosed under section 112(a) must be made by disregarding equivalents under section 112(f).

COMMENTS:

As to originally proposed § 101(a):

- (1) The newly defined term “practically useful” is proposed to incorporate a more explicit *practical application* standard into § 101.
- (2) The term “shall be entitled to” is proposed to replace “may be obtained” to provide a categorical “right to patent” provision that has been missing from Title 35 since the AIA.

- (3) The phrase “absent a finding” is proposed to again codify existing law and practice under the pre-AIA § 102 that a patent should be granted absent a reason not to do so under the law.

Before the America Invents Act was enacted, 35 U.S.C. § 102(f) contained an inventor’s right to patent provision that was not preserved intact in new § 102. If any amendment to 35 U.S.C. § 101 is to be made, it would be desirable to restore such an “inventor’s right to patent” provision to the patent statute that was at best compromised under AIA § 102. Under pre-AIA § 102, subsection (f), the patent statute provided “*A person shall be entitled to a patent unless ... he did not himself invent the subject matter sought to be patented.*” While pre-AIA § 102 was a broad provision detailing each of the various grounds for the “loss of right to patent,” all the former “loss of right to patent” provisions were stripped from § 102 when it was redrafted as an AIA novelty and prior art only provision. An amendment to § 101 to include an inventor’s right to patent provision was proposed during the legislative process that led to the AIA, but ultimately dropped because § 101 was not being otherwise amended through the AIA. In addition, the pre-AIA § 102 “right to patent” provision was regarded as the basis for the holding in the courts that placed a duty on the USPTO to advance evidence or reasoning in refusing to issue a patent on an application (*i.e.*, “A person shall be entitled to a patent unless ...”). See *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.” These holdings no longer have a clear statutory predicate, a predicate that could be restored by including in § 101 and “absent a finding” provision.

As to originally proposed § 101(b):

- (1) Instead of dividing § 101 into subsections, it is suggested to make subsection (b) a “rule of construction that would be enacted together with other proposed rules of construction.
- (2) Instead of limiting the reach of the rule to just patent eligibility, it is suggested to have the rule reach all issues of patentability and infringement.
- (3) The new rule of construction is suggested to include a separate clause requiring identification of each claim element or limitation consistent with the case law on claim construction.

The issue raised by originally proposed § 101(b) is broader than in terms of eligibility for patenting and the limitation of a new statutory rule relating only to subject matter eligibility may raise the issue of whether non-eligibility issues are subject to a different standard. The suggestion for avoiding any possible negative implication is to broadly state a rule of construction that would apply to all issues of patentability—and infringement—equally. Taking this approach would require moving this provision from § 101 to a non-codified “rule of construction” section of the legislation. This could have the salutary effect of rendering the new § 101 quite similar in length and character to § 101 under the 1952 Patent Act—and underscoring that the significant change to § 101 was the practical application standard: *a specific and substantial usefulness as applied to an area of human endeavor in a field of technology* would be a predicate to § 101 eligibility. The rule of construction is suggested to incorporate the first step in “claim construction,” the identification of the individual elements and

other limitations of the claim as a predicate to the further rule that none can be disregarded. As the Supreme Court stated (in the context of the doctrine of equivalents), “Each element contained in a patent claim is deemed material to defining the scope of the patented invention ...” *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997);

Section 112(f) Amendment:

ORIGINALLY PROPOSED:

(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 to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

SUGGESTED: Maintain as proposed.

COMMENTS:

This expansion of the reach of 35 U.S.C. § 112(f) may hold the key to the political and constitutional viability of this legislation because it should afford a categorical assurance that the protection afforded under a valid patent claim cannot preempt access to basic tools of scientific or technology work, much less a law, phenomenon, or idea on which a claimed invention is based or to which it relates.

Additional Legislative Provisions:

ORIGINALLY PROPOSED RULE OF CONSTRUCTION #1

“The provisions of section 101 shall be construed in favor of eligibility.”

SUGGESTED: Incorporate the substance of this provision as part of the proposed § 101 “right to patent” amendment above.

COMMENTS:

After the implicit exception jurisprudence is abrogated—and the various other interpretative rules are put into place—it may no longer be necessary that a further provision favoring eligibility” be explicitly included in the legislation. This may be so if for no other reason than the remaining and specific rules of construction have already achieved the desired objective of favorability. In addition, there could be a negative implication from this provision as drafted, since other conditions and requirements for patentability should presumably likewise be construed in favor of patentability. Moreover, if 35 U.S.C. § 101 is amended as suggested above (“shall be entitled to a patent, absent a finding ...”), there should not be a need for a provision of this type specific to eligibility or any other specific issue of patentability. Absent a clarification and a specifically identified, incremental purpose, deletion of this construction rule is suggested.

ORIGINALLY PROPOSED RULE OF CONSTRUCTION #2:

“No implicit or other judicially created exceptions to subject matter eligibility, including ‘abstract ideas,’ ‘laws of nature,’ or ‘natural phenomena,’ shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated. The eligibility of a claimed invention under section 101 shall be determined without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102, 103, or 112 of this title.”

SUGGESTED:

(2) 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.

(3) ELIGIBILITY DETERMINATIONS.—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.

(4) 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.

COMMENTS:

As to the abrogation language itself, a suggestion is made that would avoid the need to reference “cases” being abrogated and would focus exclusively on the “implicit exception” that is abrogated. This would be followed by a second suggested sentence that is a directive to the USPTO and the courts that new § 101 must be applied without implicit exception whatsoever.

As to the third rule of construction as proposed, it should be unnecessary since it parrots considerations from an abrogated doctrine. If it is retained, suggested language is offered that targets the highly problematic “inventive concept” jurisprudence.

The final rule of construction is intended to preserve 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)).

Effect/Effective Date:

EFFECT AND EFFECTIVE DATE.—The amendments under this Section shall take effect on the date of enactment and shall apply to any patent issued or reissued before, on, or after that date, except that this Section and the amendments made herein shall—

(1) not apply to any allegation of infringement in a civil action brought before the date of enactment of this Act.

(2) have no effect with respect to a patent issued before the date of enactment if the patentee provides written notification to the Director, within six months from the date of enactment of this Act, that this Section shall be inapplicable to the patent.

COMMENTS: The above provision would address any Takings Clause issues.

SUGGESTED LEGISLATIVE TEXT

SEC. 2. RIGHT TO PATENT; ELIGIBILITY FOR PATENTING.

(a) AMENDMENTS.—

(1) In section 100 of title 35, United States Code, insert at the end:

“(k) The term “practically useful” with respect to a claimed invention means exhibiting a specific and substantial utility as applied to an area of human endeavor within a field of technology.”

(2) In section 101 of title 35, United States Cod, strike and insert;

“§ 101. Right to patent; practical application required; eligible subject matter.

“Whoever invents or discovers any practically useful process, machine, manufacture, or composition of matter, or any useful 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.”

(3) In section 112(f) of title 35, United States Code, strike and insert:

“(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 to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.”

(4) CONFORMING AMENDMENT.—The item relating to section 101 in the table of sections for chapter 10 of title 35, United States Code, is amended to read as follows:

“§ 101. Right to patent; practical application required; eligible subject matter.”

(b) RULES OF CONSTRUCTION.—

(1) ALL CLAIM LIMITATIONS TO BE CONSIDERED.— 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, including any limitations based on the required claim construction under section 112(f), 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, provided the determination that a claim is sufficiently disclosed under section 112(a) must be made by disregarding equivalents under section 112(f).

(2) 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.

(3) ELIGIBILITY DETERMINATIONS.—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.

(4) 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.

(c) EFFECT AND EFFECTIVE DATE.—The amendments under this Section shall take effect on the date of enactment and shall apply to any patent issued or reissued before, on, or after that date, except that this Section and the amendments made herein shall—

(1) not apply to any allegation of infringement in a civil action brought before the date of enactment of this Act.

(2) have no effect with respect to a patent issued before the date of enactment if the patentee provides written notification to the Director, within six months from the date of enactment of this Act, that this Section shall be inapplicable to the patent.

SUGGESTED LEGISLATIVE COMMENTARY

The amendments to title 35, United States Code, as described in detail below operate to abrogate any “implicit exception” to the subject matter that can be regarded as being eligible for patenting in favor of new statutory requirements that (1) expand the applicability of the existing limitations on claim construction for claims containing functionally defined elements, (2) more explicitly codify the existing requirement that a claimed invention must exhibit a specific and substantial usefulness in order to be patented, and (3) impose a new limitation that such a practical utility must apply to an area of human endeavor in a field of technology.

(1) Amendments to 35 U.S.C. § 100 and § 101 – Limitation on Subject Matter Eligibility to Areas of Human Endeavor in a Field of Technology

In 35 U.S.C. § 100, a new subsection (k) defines the term “practically useful” with respect to a claimed invention as meaning a specific and substantial utility as applied to an area of human endeavor within a field of technology. This definition is then incorporated into an amended 35 U.S.C. § 101.

In 35 U.S.C. § 101, five changes are made to the text of § 101 as enacted under the 1952 Patent Act. The text of amended § 101, as compared to the text of § 101 as enacted under the 1952 Patent Act:

(1) strikes the words “Inventions patentable” and inserts the words “Right to patent; practical application required; eligible subject matter” in the title of the section,

(2) strikes the words “new and” at both occurrences and inserts the word “practically”;

(3) strikes the words “may obtain” and inserts the words “shall be entitled to”;

(4) strikes the words “subject to the” and inserts the words “absent a finding that one or more”; and

(5) after the word “title” inserts the words “have not been met”.

In addition to these changes, the entry in the table of sections for § 101 is changed to conform to the amendment to the title described above.

Compared to the text of § 101 enacted under the 1952 Patent Act, amended § 101 and the new definition under § 100(k) read:

§ 101. ~~Inventions patentable.~~ Right to patent; practical application required; eligible subject matter.

Whoever invents or discovers any ~~new and~~ practically useful process, machine, manufacture, or composition of matter, or any ~~new and~~ practically 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.

§ 100. Definitions.

...
(k) The term “practically useful” with respect to a claimed invention means a specific and substantial utility as applied to an area of human endeavor within a field of technology.

The change to the title of 35 U.S.C. § 101 reflects the addition to § 101 of two new elements beyond its role under the 1952 Patent Act of setting for subject matter eligible for patenting, *i.e.*, the “Inventions patentable.” The first of these is a new inventor’s right to patent provision that, as explained below, was present in 35 U.S.C. § 102 prior to the enactment of the America Inventions Act and the second is a requirement that a claimed invention represent a practically useful application that contributes to a field of technology to qualify for patenting.

A second change to § 101 eliminates the redundant term “new” in two locations. The courts have held that the term “new” under § 101 represents a redundant reference to the “novelty” requirement under 35 U.S.C. § 102. *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.”

The removal of “new” from § 101, thus, eliminates any possibility that this term could be construed different under § 101 from the 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 appreciated to so exist. Thus, 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. Bariant, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987).

A third change modifies the word “useful” with the adverb “practically” in two locations. The result of this modification is to codify decisions of the courts holding that the utility required for a claimed invention to be patentable must be a specific and substantial usefulness, *i.e.*, a claimed invention must be *practically useful*. The term “practically useful” is now defined in 35 U.S.C. § 100(k) with respect to the subject matter defined by a claim. This new definition specifies that practically useful subject matter must exhibit “a specific and substantial utility as applied to an area of human endeavor within a field of technology”

The “practical utility” definition, in part, codifies the decisions of the courts that have required a specific and substantial usefulness for a claimed invention to be patentable under § 101. In this regard, *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005) explains and adopts the Supreme Court precedent in *Brenner v. Manson*, 383 U.S. 519 (1966) by holding that the utility that must be specific, practical, and substantial, but with the terms “practical” and “substantial” being considered synonymous. 421 F.3d at 1371, including footnote 4, “this court considered the phrase ‘practical utility’ to be synonymous with the phrase ‘substantial utility.’”

The new definition in § 100(k) restricts the nature of the utility that is required to utility *as applied to an area of human endeavor within a field of technology*. This portion of the new definition has the effect of imposing a *practical application* limitation on the subject matter that can be validly patented.

Areas of human endeavor include areas in which natural laws, natural phenomena, and abstract ideas are applied. For the purposes of amended § 101, areas of human endeavor are those where humankind has intervened in the natural world to produce new applications of laws, phenomena, or ideas exhibiting some specific and substantial utility. 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 natural product could be patented if each of the additional patentability requirements of inherent novelty, non-obviousness, sufficiency of disclosure, and claim definiteness were also satisfied.

A fourth change imports into § 101 the new definition in § 100(k) that further confines a practical utility to an application within a field of technology. The imposition of an explicit “field of technology” limitation on the areas of human endeavor defining subject matter eligible for patenting under § 101 assures that patentable subject matter under title 35 will fall within useful arts, consistent with 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.”

A final change introduces into amended § 101 an “inventor’s right to patent provision specifying that the inventor of a claimed invention shall be entitled to a patent on the claimed invention absent a finding that one or more requirements under title 35 have not been met. Under 35 U.S.C. § 102(f) enacted under the 1952 Patent Act, Congress provided such an inventor’s “right to patent” provisions, “A person shall be entitled to a patent unless ... he did not himself invent the subject matter sought to be patented,” that was not reenacted under the American Invents Act. The provisions § 102 enacted under the 1952 Patent Act, providing that “[a] person shall be entitled to a patent unless” the specified requirements for novelty and “loss of right to patent” were not met, formed a basis for the courts to hold that some finding must be made, based upon facts established or reasoning articulated, in order to deny an inventor a patent for a claimed invention. *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.”

This final change to § 101 reenacts the “right to patent” provision that was not reenacted under the America Invents Act when § 102 was amended to confine § 102 to issues of novelty and prior art. It, thus, reflects no change in the law or in the practice in the United States Patent and Trademark Office, or the courts, from the 1952 Patent Act.

(2) Amendments to 35 U.S.C. § 112(f) – Interpretation of Functionally Characterized Claim Elements

In 35 U.S.C. § 112(f), two limitations of the applicability of this section are removed: (1) a limitation to claims drafted as combinations of elements and (2) a limitation that has been construed by the courts to presumptive limit the applicability of this subsection to claims containing the words “means for” or “step for.” Compared to § 112(f) as enacted under the 1952 Patent Act, amended § 112(f):

(1) strikes the words “Element in a Claim to a Combination” and inserts “Required Claim Construction.” in the title for the subsection;

(2) strikes the words “for a combination may be” to remove this first limitation;

(3) strikes the words “a means or step for performing” to remove the second limitation;
and

(4) strikes the words “and such claim” to conform the claim to the new grammatical structure.

Compared to the text of § 112(f) enacted under the 1952 Patent Act, amended § 112(f) thus reads:

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

Under amended § 112(f), the new requirement for claim construction applies to all claims with elements that are found to be functionally defined. The amendment removes the limitation under § 121(f) to so-called “combination claims” that contain multiple discrete elements. Thus, amended § 112(f) applies equally to “combination claims” and so-called “single means” claims, (*i.e.*, a claim “reciting only a single element instead of a combination.” *In re Hyatt*, 708 F. 2d 712 (Fed. Cir. 1983)).

Amended § 112(f) also eliminates the presumptive inapplicability 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.

Amended § 112(f) now requires 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 to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. 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) are used to determine whether § 112(f) applies to a claim element.

The amendment to § 112(f), by applying to all claims construed to contain functionally defined elements, precludes the possibility that any patent claim, properly interpreted under amended § 112(f)—even if deemed directed to a natural law or phenomenon or other abstract idea—could preempt access to basic tools of scientific and technological work. Through this limitation on claim construction under § 112, Congress has provided a new and fully statutory mechanism to assure 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.” *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

With the amendment to § 112, Congress has now reflected explicitly in the patent statute itself—through a limitation on claim construction—the policy that “monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.” *Mayo Collaborative v. Prometheus Labs.*, 132 S. Ct. 1289, 1293 (2012). Congress has, thus, assured that the patent statute itself will now operate so that the “patent law not inhibit further discovery by improperly tying up the future use of laws of nature.” 132 S. Ct. at 1301.

Through an “implicit exception” to subject matter that could be regarded as eligible for patenting under § 101, the Supreme Court heretofore had mandated that so-called “preemptive” claims directed to a law or phenomenon of nature or other abstract idea be excluded from eligibility for patenting. “We have described the concern that drives this exclusionary principle as one of pre-emption.” *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S. Ct. 2347, 2354 (2014). A claim has been considered by the courts to be “preemptive,” if the claim were *directed to an “abstract idea”* (such as the concept of “risk hedging”), whenever the claim would have permitted the protection afforded under the patent to “pre-empt use of [the concept] in all fields, and would effectively grant a monopoly over an abstract idea.” *Bilski v. Kappos*, 130 Sup.Ct. 3218, 3231 (2010). The amendment to § 112(f) moots this concern because it would limit a valid patent claim to, at most, the structure, material, or acts disclosed in the specification for carrying out the claimed invention, *e.g.*, performing the steps of any process being claimed.

An inventor heretofore presenting a claim that would lack a sufficient description of an invention under 35 U.S.C. § 112(a), on account of functional language present in an element of the claim, would now come under the remedial provisions of amended § 112(f) in determining if the § 112(a)-required “written description” in the patent’s specification were present. Such claims, when their functional elements are construed under § 112(f), can have a sufficient description under § 112(a) and, thus, be patentable.

An inventor presenting a “single means” claim that might heretofore have been invalid patent under § 112(a) on account of an insufficient disclosure under *O’Reilly et al. v. Morse et al.*, 56 U.S. 62, 113 (1853)—because the patent “claims an exclusive right to use a manner and process which [the patent specification] has not described and indeed [the inventor] had not invented, and *therefore could not describe* when [the inventor] obtained his patent”—will have the scope of such a “single means” claim limited to the corresponding structure, material, or acts disclosed in the specification. In so limiting the claim, the § 112(a) insufficient disclosure may be mooted, such that the holding under *O’Reilly et al. v. Morse et al.* would not be applicable to the claim.

Similarly, the holding in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946) with respect to “combination claims” can be mooted under amended § 112(f) without regard whether, as in *Halliburton*, the claim language employed the words “mean for” in defining the functional claim element. Because the crucial elements of the Walker patent claims at issue in *Halliburton* were not subject to the remedial provisions under § 112(f) to define the scope of protection under the patent (*i.e.*, § 112(f) was enacted in 1952, in part in response to the holding in *Halliburton*), the Walker patent, had it been found valid, would have impermissibly secured “*such broad rights to bar the use of all devices now or hereafter known which could*” perform the function specified in the claim element.” 329 U.S. at 13. As such, the Walker claim could not be found valid, as having a sufficient disclosure under § 112(a). Had the Walker claims been subject to the required claim construction limitation under § 112(f) confining the claim to the corresponding structures and materials disclosed in the Walker specification, the required “written description” and enablement of the disclosed structures/materials present in the specification, could have resulted in a § 112(a)-sufficient disclosure of the subject matter to which the claim was limited.

The applicability of § 112(f) does not otherwise modify or negate the requirements under § 112(a) and § 112(b) regarding sufficiency of disclosure and claim definiteness. “[S]ection 112[(f)] does not exempt an applicant from the requirements of [subsections (a) and (b)] of that section. Although [§ 112(f)] statutorily provides that one may use means-plus-function language in a claim, one is still subject to the [§ 112(b)] requirement that a claim ‘particularly point out and distinctly claim’ the invention. Therefore, if one employs means-plus-function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by [§ 112(b)].” *In re Donaldson Co., Inc.*, 16 F.3d 1189, 1195 (Fed. Cir. 1994).

As noted below, with respect to the rules of construction being enacted, the equivalents to which a claim construed under § 112(f) covers are of no relevance to the determination of whether the claim contains a § 112(a)-sufficient disclosure. This is consistent with the rule of construction that applied to § 112(a) determinations for a claim that is infringed under the so-called “doctrine of equivalents.”

(3) Rules of Construction

The Act, in addition to the substantive amendments to § 100, § 101, and § 112, enacts three rules of construction with respect to the issues of subject matter eligibility and sufficiency of disclosure:

(1) ALL CLAIM LIMITATIONS TO BE CONSIDERED.— 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, including any limitations based on the required claim construction under section 112(f), 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, provided the determination that a

claim is sufficiently disclosed under section 112(a) must be made by disregarding equivalents under section 112(f).

(2) 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.

(3) ELIGIBILITY DETERMINATIONS.—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.

(4) 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.

The first of these three rules of construction applies broadly to issues of patentability and patent validity, as well as issues of patent infringement. This first rule of construction 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 claim to patentable subject matter.

For a claim element construed under § 112(f), the presence of a sufficient disclosure under § 112(a) is determined based on the structure, material, or acts to which the claim element is limited. For this purpose, the equivalents of any such structure, material, or acts are not considered as part of the disclosure sufficiency determination under § 112(a), *i.e.*, the patent specification is not required to provide an additional written description or an enabling disclosure otherwise of such equivalent structures, materials, or acts to comply with the requirements of § 112(a).

The second of these rules of construction constitutes an abrogation of any implicit exception to the subject matter expressly defined in amended § 101 as being eligible for patenting. Thus, for a claimed invention found to be directed to a natural law or phenomenon or an abstract idea, such claim—if it meets the express requirements under amended § 101—must be regarded as defining subject matter eligible for patenting. For this reason, amended § 101 must be applied as though no implicit exception to subject matter eligible for patenting is present in amended § 101. This second rule of construction 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. At the same time, the Act addresses the policy issues that led to the judicial imposition of such an implicit exception through the amendments to § 100, § 101, and § 112(f), such that a properly interpreted claim can no longer be construed in a preemptive manner with respect to the basic tools of scientific and technological work, such as any law, phenomenon, or idea.

The third of these rules of construction eliminates any consideration of the manner in which the invention was made or the inventiveness of any claim element in the determine of subject matter eligibility under § 101. 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.

The final rule of construction is intended to preserve 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 USPTO might refuse to grant a patent to a person otherwise entitled to a patent for a claimed invention under 35 U.S.C. § 101.

(4) Effect and Effective Date.

The amendments to title 35, United States Code, and the rules of construction are given immediate effect and apply to patents issued before, on, or after the date of enactment except with respect to any civil action brought before the date of enactment or any patent issued before the date of enactment where the patent owner has elected in writing, within six months for the date of enactment that the law shall be inapplicable. The notice of applicability must be given to the United States Patent and Trademark Office.