



THE NAPLES ROUNDTABLE

Exploring Ways to Strengthen & Improve the Patent System

IN THE QUEST TO STRENGTHEN THE U.S. PATENT SYSTEM: THE IMPERATIVE FOR ADDRESSING THE “IMPLICIT EXCEPTION” ADMINISTRATIVELY

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*PHOENIX ISSUE III. IS THERE A PROBLEM WITH SECTION 101 DECISIONS AND WILL THERE
LIKELY BE ANY LEGISLATIVE FIX? IF NOT, THEN WHAT IF ANYTHING CAN BE DONE?*

Summary and Overview

Notwithstanding the efforts of all manner of bar and trade associations to address the issues raised by the Supreme Court jurisprudence imposing an “implicit exception” to the subject matter that Congress has indicated in 35 U.S.C. § 101 can qualify for patent protection, no single legislative proposal has yet emerged that has garnered the consensus as to its merits that provides the necessary predicate for a successful legislative effort that could lead towards its enactment. These and other complications with any near-term legislative solution to the entirely unacceptable state of affairs resulting from the judicially imposed *Mayo/Alice* two-part test for denying patent eligibility suggest that other remedial avenues should be considered to move towards the goal of removing from the U.S. patent law the inherent unpredictability, indeed outright arbitrariness, of subject matter eligibility analyses resulting from the Court’s precedents.

The Supreme Court itself was presented with—but declined to consider—a near-ideal vehicle for addressing the judicial mess it had made of the subject matter eligibility analysis in the *Ariosa v. Sequenom* petition for certiorari. Amici, specifically Eli Lilly and Company, *et al.*, had urged the Court to overrule its entire line of jurisprudence declaring the ineligibility for patenting of inventions directed to a law/product of nature, natural/physical phenomenon, or other type of abstract idea or concept—in favor of reliance on *statutory requirements* for patentability, namely the novelty requirement under 35 U.S.C. § 102 under which inventions dominating a law/product of nature or natural/physical phenomenon are inherently anticipated (*i.e.*, such subject matter inherently lacks novelty, even at the time newly discovered) and the requirement for a sufficient disclosure under 35 U.S.C. § 112 that—as the Supreme Court itself held in *O’Reilly v. Morse* and *Halliburton v. Walker*—does not allow protection for claims merely setting out a function, result, mechanism, or property rather than the structures, materials, or acts that carry out the function, achieve the result, operate under the mechanism, or exhibit the property.

The attached paper outlines § 112 examination guidance that the United States Patent and Trademark Office might adopt to address the “implicit exception” mess until Congress or the Court acts—and largely moot the need for any *Mayo/Alice* “implicit exception” analysis.

Pre-Conference Discussion Draft

SUBMISSION ADDRESSING THE JANUARY 7, 2019 USPTO NOTICE¹ SEEKING COMMENTS ON 35 U.S.C. § 112 EXAMINATION GUIDANCE

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Introduction and Summary

The United States Patent and Trademark Office published two patent examination guidance proposals on January 7, 2019. These proposals address subjects of the utmost importance to the patent system. One of the proposals, which is the subject of comments provided in this paper, offers new guidance on the sufficiency of a patent application's disclosure under 35 U.S.C. § 112. The other proposal deals with limits on subject matter eligibility for patenting.² While these two proposals lay out guidance on nominally separate patentability issues, they address intimately related aspects of the patent law that focus on a common principle: *valid patents should not protect ideas or concepts, but limit protection afforded to the practically useful products and processes specifically described in the application for patent.*

The present submission offers comments on—and suggested revisions to—the proposed new guideposts for examining patent applications under § 112. This submission further proposes changes to the patent examination process as it relates to both disclosure sufficiency issues under § 112 and subject matter eligibility issues under Supreme Court precedents. In particular, it urges that the Office revise its proposed § 112 guidance in ways that might moot the need for examiners to routinely address subject matter eligibility under the second proposal.

Specifically, proposed revisions herein urge that the Office direct patent examiners to determine that *each discrete element* of an *independent claim* expressed as a *combination of elements* is to be presumed *crucial* to the claim's novelty and non-obviousness. Given this presumption, if such an element is found to be *functionally defined*, the claim would be rendered unpatentable under 35 U.S.C. § 112(a)—based on the Supreme Court's holding in its *Halliburton* decision—absent applicability of 35 U.S.C. § 112(f) to limit the coverage of each such functional element to the application's disclosed structures, materials, or acts corresponding to the defined function. With this presumption that *§ 112(a) patentability requires § 112(f) applicability*, the Office should then guide examiners to determine that the *broadest reasonable interpretation* (BRI) of the functionally defined limitations in such a claim *requires that § 112(f) govern the interpretation of the claim for examination purposes* because it is the *sole possible* interpretation that could result in the claim being patentable—*i.e.*, any interpretation that would result in the claim being unpatentable, while a *possible* interpretation, should not be found to be a *reasonable* one. Such guidance would then require the examiner to place responsibility on the applicant to identify the disclosed structures to which each functionally defined element in the claim must be limited or to otherwise demonstrate that such functionally defined elements would be understood in the art to be structurally limited, so that the claim could be found patentable under § 112(a).

¹ See <https://www.govinfo.gov/content/pkg/FR-2019-01-07/pdf/2018-28282.pdf>.

² 2019 Revised Patent Subject Matter Eligibility Guidance, <https://www.govinfo.gov/content/pkg/FR-2019-01-07/pdf/2018-28283.pdf>.

Background

The Office’s two recent guidance proposals³ address separate legal mechanisms designed to assure that valid patent claims must do more than define a claimed invention in conceptual or otherwise functional terms. Whether couched as an issue of sufficiency of disclosure or subject matter eligibility for patenting, the guidance seeks to assure that valid patent claims should not protect an abstract idea or concept, *i.e.*, a functional characterization of an invention.

Put another way, for the patent system to serve its constitutional purpose of promoting progress in useful arts, some limitation in the patent law must operate to prevent inventors from securing such broad protection that valid patent claims cover what an invention *does* and not just what the inventor’s application discloses that the invention *was*. According to the Supreme Court’s jurisprudence limiting subject matter eligible for patenting—which the Court has tied to its constitutional understanding of the purpose of the patent system—patents should not require payment of tribute to inventors in order for the public to gain access to the basic tools of science and technology.⁴

Instead, the Supreme Court’s jurisprudence can be read to provide that Congress was free to use its constitutional authorization to provide inventors strong and commercially meaningful patent protection, but only protection based on the embodiments disclosed in the specification of the patent, *i.e.*, the structures, materials, or acts that represent a practically useful application that can be shown to be novel and non-obvious.⁵

³ The presently proposed guidance, which is captioned “Examining Computer-Implemented Functional Claim Limitations for Compliance With 35 U.S.C. § 112,” is confined to addressing one specific area of technology. However, all the principles articulated in the proposed guidance are general ones with equal applicability across all areas of technology. Indeed, in support of some of the key considerations set out in the guidance, the proposed guidance relies upon a Federal Circuit decision rendered with respect the technology that has no relationship to computing, *i.e.*, *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc). The Office should consider whether the revisions to the proposed guidance in this paper merit adoption irrespective of the technical field to which a claimed invention relates.

⁴ The Supreme Court has set out an “implicit exception” to the subject matter that can be regarded as eligible for patenting under the patent statute under 35 U.S.C. § 101. This exception applies to “[l]aws of nature, natural phenomena, and abstract ideas [that] are the basic tools of scientific and technological work.” The Court has held “monopolization 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. ... [S]ee 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 further discovery by improperly tying up the future use of these building blocks of human ingenuity.” *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S. Ct. 2347, 2354 (2014). [Internal citations and quotations are omitted.]

⁵ In *Alice, supra*, at 134 S.Ct. 2354-2354, the Supreme Court emphasized the importance of limiting the “implicit exception” as it could otherwise negate an effective patent system, “At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. ... At some level, all inventions... embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. ... Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept. [A]pplication[s] of such concepts to a new and useful end, we have said, remain eligible for patent protection. ... Accordingly, ... we must distinguish between patents that claim the buildin[g] block[s] of human ingenuity and those that integrate the building blocks into something more, ... thereby transform[ing] them into a patent-eligible invention, ... The former would risk disproportionately tying up the use of the underlying ideas, ... and are therefore ineligible for patent protection. The latter pose no comparable risk of pre-emption, and therefore remain eligible for the monopoly granted under our patent laws.” [Internal citations and quotations are omitted.]

Conceptual or “functionally defined” claims contain one or more crucial elements that set out—in whole or in part—no more than *the function the invention is to perform, the mechanism by which the invention is to operate, the effects the invention is to produce, or the result the invention is to achieve*.⁶ In such functionally defined claims, structural limitations are at least partially absent from one or more crucial claim elements. Absent some limiting rule of construction, these functionally defined claims would effectively extend patent protection to all means for accomplishing a particular end.⁷ In effect, such claims would exhibit precisely the defect bemoaned by the Supreme Court in its *Alice* decision on subject matter eligibility for patenting—as well as the various decisions to which the Supreme Court cites in support of its *Alice* holding.⁸

To effect essentially the same end, the Supreme Court has explained that the statutory requirements for a sufficient disclosure—now codified in 35 U.S.C. § 112 of the Patent Act of 1952—invalidate claims drafted broadly enough to cover whatever performs a function stated in the claims, instead of restricting the scope of protection to the structures, materials, or acts for achieving the function that are disclosed in the patent specification.

These Supreme Court decisions on disclosure sufficiency address the complete waterfront of claim types in equal measure—product claims as well as process claims, and so-called “single means” claims,⁹ as well as “combination inventions,” *i.e.*, inventions claimed in terms of multiple discrete elements.

⁶ The reference in these comments to “functionally defined claim elements” or “functionally defined claims” includes claims drafted with each of the various linguistic mechanisms, illustrated in the text above, such that the patent draftsman avoids any explicit definition of what the invention actual is, other than in terms of what the invention does. It does not reference a claim with elements or other limitations that have an established structural meaning, even if the wording of the claim suggests function as well as structure. Although terminology may reference what on its face might appear to constitute merely a *function* to be performed, that terminology may be “understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure.” *Williamson v. Citrix Online, LLC*, 792 F. 3d 1339, 1348 (Fed. Cir. 2015). In addition, functionally defined elements can be present, even if some reference to structure also limits the claim, *e.g.*, “a functional claim exists not only when a claim is ‘wholly’ functional, if that is ever true, but also when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty.” *Gen. Electric Co. v. Wabash Co.*, 304 US 364, 371 (1938).

⁷ The Federal Circuit precedents addressing functionally defined claims have largely clarified that the analysis for sufficiency of the disclosure under § 112(a) addresses whether a person skilled in the art reading the patent specification would understand from the disclosure that the inventor had possession of the invention, *i.e.*, had described what the invention is in terms other than what the invention does. The proposed guidance cites to the leading case at the Federal Circuit setting out this disclosure sufficiency requirement, commonly referenced as the “written description” requirement, “*Ariad Pharm., Inc. v. Eli Lilly and Co.* ... (discussing the problem of functional claims defining a genus that ‘simply claim a desired result ... without describing species that achieve that result’).”

⁸ *Alice*, *supra*, citing to *Bilski v. Kappos*, 130 S. Ct. 3218. 3223-3224 (2010), *Mayo Collaborative Services v. Prometheus Labs.*, 132 S. Ct. 1289 (2012), and *Ass’n for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013).

⁹ “A ‘single means claim’ is a claim drafted in ‘means-plus-function’ format yet reciting only a single element instead of a combination. ... See ... *General Elec. Co. v. Wabash Appl. Corp.*, 304 U.S. 364, 371 (1938) (‘A patentee may not broaden his product claims by describing the product in terms of function.’).” *Amgen v. Chugai*, 13 USPQ2d 1737, 1774 (DC Mass. 1989), Memorandum and Order of Magistrate Judge Patti Saris (reported at *Biotechnology Law Report* Vol. 9, No. 1, <https://doi.org/10.1089/blr.1990.9.25>)

The Court first addressed the “insufficient disclosure” bar to validity in the context of single-means claiming¹⁰ 165 years ago in *O’Reilly v. Morse*, 56 U.S. 62 (1854).¹¹ Nearly a century later, the Court clarified that the same disclosure insufficiency defect invalidated claims containing multiple, discrete elements (*i.e.*, “combination claims”) where functional language was used to define the *crucial* elements of an allegedly novel combination, *i.e.*, those elements imparting novelty and non-obviousness to the combination. This holding appeared in the seminal decision, *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946).¹²

When Congress enacted the sixth paragraph of 35 U.S.C. § 112 (now § 112(f)) as part of the 1952 Patent Act, its intention was not to *overrule* the holdings of either *O’Reilly* or *Halliburton*. Rather than overrule the Court’s invalidation of combination claims in which *crucial* elements were functionally defined, Congress elected in enacting § 112(f) to *moot* such invalidity holdings by imposing a new—and *mandatory*—statutory claim interpretation limitation on *all* functionally defined elements, “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*.”¹³

While the statute made use of the terms “means for” and “step for” in characterizing the claims subject to this statutory limitation on construing claims, nothing in the legislative process that led to the 1952 Patent Act indicates that Congress intended the applicability of the new statute would in any way at all depend on whether or not the text of the claim at issue actually included the words “means for” or “step for.” Rather, congressional intent appears to reflect that § 112(f) was to address functional claiming more broadly, even categorically.¹⁴ In the legislative

¹⁰ See *In re Hyatt*, 708 F. 2d 712, 714 (Fed. Cir. 1983), “The long-recognized problem with a single means claim is that it covers every conceivable means for achieving the stated result, while the specification discloses at most only those means known to the inventor. See *O’Reilly v. Morse*, 56 U.S. 62, 112, (1853). Thus, the claim is properly rejected for what used to be known as ‘undue breadth,’ but has since been appreciated as being, more accurately, based on the first paragraph of § 112 [now § 112(a)].”

¹¹ The Morse “single means” claim was directed to “the use of the motive power of the electric or galvanic current ... however developed for marking or printing intelligible characters, signs, or letters, at any distances, being a new application of that power of which I claim to be the first inventor or discoverer.” 52 U.S. (15 How.) 86. While the Morse claim was nominally limited to the *practical applications* of electromagnetism, it failed to describe what those applications were other than in terms of the result that they would achieve, *i.e.*, marking or printing intelligible characters at distances.

¹² “The language of the claim thus describes this most crucial element in the ‘new’ combination in terms of what it will do rather than in terms of its own physical characteristics or its arrangement in the new combination apparatus. We have held that a claim with such a description of a product is invalid...” *Id.*, 329 U.S. 9.

¹³ 35 U.S.C. § 112(f) [Emphasis added.]

¹⁴ The (unofficially) authoritative Federico Commentary on the 1952 Patent Act addressing the role § 112(f) was to play confirms that it was a basis for *mooting* the holding in *Halliburton*, not overruling it, while leaving in place a categorical bar to “single means” claiming:

“The last paragraph of section 112 *relating to so-called functional claims* is new. It provides that an element of a claim for a combination (and a combination may be not only a combination of mechanical elements, but also a combination of substances in a composition claim, or steps in a process claim) may be expressed as a means or step for performing a specified function, without the recital of structure, material or acts in support thereof. It is unquestionable that some measure of greater liberality in the use of functional expressions in combination claims is authorized than had been permitted by some court decisions, and that *decisions such as that in Halliburton Oil Well Cementing Co. v. Walker*, 67 S.Ct. 6, 329 U.S. 191 L. Ed. 3 (1946), are modified or rendered obsolete, but the exact limits of the enlargement remain to be determined. The language specifies ‘an’ element, which means

history for the 1952 Patent Act, § 112(f) was simply characterized as a “new paragraph relating to *functional claims*.” [Emphasis added.]¹⁵

Indeed, the best understanding of the enactment of § 112(f) is that it represented a remedial legislative effort. Congress was ameliorating the effects of *Halliburton*-mandated invalidity of a claim by imposing a binary outcome: *For claims with functionally defined elements, specifically those deemed to be crucial ones under the Halliburton standard, either § 112(f) necessarily applies and thereby limits the functional element to the disclosed structures, materials, or acts described in the patent specification that correspond to the function or the claim is invalid for insufficient disclosure under the aforementioned Supreme Court precedents.*

Thus, the controlling precedents—represented by the *Halliburton* and *O’Reilly* holdings—leave no wiggle room. If a crucial claim element that was functionally defined could be drafted in a manner to avoid the application of § 112(f), then the claim would lack a sufficient § 112(a) disclosure and would be invalid.

USPTO Guidance Should Apply § 112(f) To Claim Interpretation Consistent With BRI

Over several decades, Federal Circuit precedents have failed to fully effect the remedial purpose of § 112(f). Most specifically, Federal Circuit precedents are essentially silent on the role of § 112(f) as a “safe harbor” that operates to salvage the validity of what otherwise would be invalid claims under § 112(a) based upon the *Halliburton* holding.

Had the Federal Circuit fully embraced § 112(f)’s remedial purpose, its precedents would have provided that this subsection must be applied to limit otherwise § 112(a) invalid, functionally defined claim across the board—with no less than a “strong presumption” supportive of § 112(f)’s broad applicability. Perplexingly, the Federal Circuit has done just the opposite. The Federal Circuit has imposed a presumption—and until very recently a “strong presumption”—that § 112(f) would be *inapplicable* to a claim element absent the claim literally reciting the words “means for” or “step for.”¹⁶ Even today, Federal Circuit law maintains such a

‘any’ element, and by this language, as well as by application of the general rule that the singular includes the plural, it follows that more than one of the elements of a combination claim may be expressed as different ‘means’ plus statements of function. The language does not go so far as to permit a so-called single means claim, that is a claim which recites merely one means plus a statement of function and nothing else. Attempts to evade this by adding purely nominal elements to such a claim will undoubtedly be condemned. The paragraph ends by stating that such a claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. This relates primarily to the construction of such claims for the purpose of determining when the claim is infringed (note the use of the word ‘cover’), and would not appear to have much, if any, applicability in determining the patentability of such claims over the prior art, that is, the Patent Office is not authorized to allow a claim which ‘reads on’ the prior art.” [Emphasis added.] P. J. Federico, *Commentary on the New Patent Act*, 75 J. Pat. & Tm. Off. Soc’y 161, 186 (1993), available for download at <https://heionline.org/HOL/LandingPage?handle=hein.journals/jpatos75&div=36>.

¹⁵ “[W]e are guided by the familiar canon of statutory construction that remedial legislation should be construed broadly to effectuate its purposes.” *Tcherepnin v. Knight*, 389 US 332, 336 (1967).

¹⁶ The proposed guidance lays out this history of antipathy: “The U.S. Court of Appeals for the Federal Circuit (‘Federal Circuit’) has recognized a problem with broad functional claiming without adequate structural support in the specification. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (en banc) (overruling the Federal Circuit’s previous application of a ‘strong’ presumption that claim limitations lacking the

§ 112(f) inapplicability presumption where the words “means for” do not appear in the claim element.¹⁷

The motivation for the Federal Circuit’s seeming antipathy to limiting functionally defined claims to disclosed structures under § 112(f) was not part of a judicial strategy to then routinely invalidate such functionally defined claims as being in violation of the *Halliburton* holding. Rather, when the court found § 112(f) inapplicable to such claims, its decisions routinely permit those claims to retain their presumptive “not invalid” status without any further analysis as to whether the *Halliburton* doctrine were to be applied to invalidate them.

The Federal Circuit’s dual inaction (in neither subjecting functionally defined claims to § 112(f)’s limitation on what they can cover nor invalidating them as being insufficiently disclosed under § 112(a)) has obscured the 1952 Patent Act’s *comprehensive § 112(a)/§ 112(f) statutory constraints barring conceptual or other functional claiming*. This inaction has facilitated the Supreme Court’s recent musings that the patent statute itself is either unreliable or incomplete as a vehicle for tempering conceptual or other functional claims.¹⁸ The claims that were being issued by the Office and being enforced in the courts—without being § 112(f)-constrained pursuant to Federal Circuit decisions—left the door open for the Supreme Court to impose its *extra-statutory*, “*implicit exception*” to *subject matter eligibility for patenting*.

To at least some extent, the Supreme Court’s judicial imposition of its non-statutory bar to patenting simply invalidates claims that the patent statute itself should have invalidated under § 112(a), if § 112(f)’s limitations were inapplicable.¹⁹ In addition, the Federal Circuit’s § 112(f)-related presumptions focusing on the presence or absence of “magic words” in the claims fed into another Supreme Court musing—that the patent professional’s “draftsman’s art” required some extra-statutory fettering.²⁰

While the Federal Circuit has now walked back its *strong presumption* jurisprudence as it relates to § 112(f), the Court has yet to reconcile the seeming inconsistency in its decisions that have the effect of circumventing § 112(f)’s “safe harbor,” but then failing to recognize the claims were no longer safe from § 112(a) invalidation. This lack of reconciliation is made all the more

word ‘means’ are not subject to § 112(f) to address the resulting ‘proliferation of functional claiming untethered to [§ 112(f)] and free of the strictures set forth in the statute’)...” 84 Fed. Reg. 57.

¹⁷ See again *Williamson v. Citrix Online, LLC*, 792 F. 3d 1339, 1348-1349 (Fed. Cir. 2015) (en banc). Also, “[w]hen the claim drafter has not signaled his intent to invoke [§ 112(f)] by using the term ‘means,’ we are unwilling to apply that provision *without a showing that the limitation essentially is devoid of anything that can be construed as structure*.” *Flo Healthcare Solutions, LLC v. Kappos*, 697 F.3d 1367, 1374 (Fed. Cir.2012).

¹⁸ “[T]o shift the patent-eligibility inquiry entirely to these [non-eligibility] sections [of the 1952 Patent Act] risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.” *Myriad, supra*, at 132 S.Ct. 1304

¹⁹ For a somewhat provocative analysis of the relationship between claimed inventions found to lack subject matter eligibility under Supreme Court precedents and the disclosure sufficiency issues such claims raise under § 112(a) (as well as 35 U.S.C. § 102), see Robert A. Armitage, “Whither Patenting Of Biomedical Inventions After *Mayo*, *Myriad*, And Now *Alice*,” 33rd ABA IPL Section Intellectual Property Law Conference (April 18-20, 2018), available at <https://pdfs.semanticscholar.org/3f17/b28128053e80b241c5ed57cad9e669c5c22c.pdf>.

²⁰ See *Alice, supra*, at 134 S.Ct. 2359, urging that that the courts should not “make the determination of patent eligibility ‘depend simply on the draftsman’s art,’ ... thereby eviscerating the rule that “[I]aws of nature, natural phenomena, and abstract ideas are not patentable...” [Internal citations are omitted.]

inexplicable given that the § 112(a) disclosure sufficiency standard set by the Supreme Court in *Halliburton* is fully consonant with the Federal Circuit’s own long line of cases invalidating patents for want of an adequate “written description” under § 112(a), *i.e.*, when “single means” claims have been found to functionally characterize what the invention *does* rather than specifically describe what the invention *was*.²¹

The Federal Circuit’s continuing antipathy towards simply applying § 112(f) as a remedial “safe harbor,” *i.e.*, to protect from invalidation otherwise invalid claims under § 112(a), suggests that the Office in its guidance to examiners with respect to § 112(f)’s applicability should—at a minimum—assure that any homage owed to Federal Circuit § 112(f) precedents does not come at the expense of fidelity to longstanding Supreme Court § 112(a) law on unpatentability. For this reason, the revisions set forth herein to the Office’s proposed guidance take a fresh look at the nature of the § 112(f) guidance that might be appropriate for the conduct of patent examination.

In drafting its guidance, the Office proposed that the “presumptions” as to applicability or inapplicability of § 112(f) currently dictated under Federal Circuit precedents should be applied in the patent examination context. In addition, like the Federal Circuit itself, the proposed guidance does not take the next step, which would appear necessary for the Office to be faithful to Supreme Court precedents, *by acknowledging that the Halliburton standard for § 112(a) sufficiency of disclosure then should apply to invalidate functionally defined claims if the “safe harbor” of § 112(f) is found to be unavailable for one or more crucial claim limitations.*

However, as detailed below, the Federal Circuit’s presumptions can be relevant—or can be irrelevant—to patent examination depending on the methodology the Office employs to determine the *broadest reasonable interpretation* for a claim under examination. Specifically, if the comments in this paper are accepted by the Office, its guidance could provide that examiners are not necessarily tied to the Federal Circuit’s presumption-bound view of § 112(f)’s applicability. As detailed below, the Office has another course open to it that is more consistent with its obligation to assure Supreme Court precedents are not disregarded.

In this respect, *the Office is urged to conclude that these § 112(f)-related “presumptions” are of no relevance to the work of the Office in examining claims.* Whatever applicability the Federal Circuit’s “presumptions” relative to § 112(f) have in the construing claims *for validity purposes*, it does not follow that they dictate any constraints on the patent examiner’s work of *determining patentability*. At least two considerations support this lack of relevance.

²¹ The Federal Circuit’s views on the invalidity of “single means” claims, as required under the Supreme Court’s *O’Reilly* holding, can be best understood from the court’s holding in *Regents of University of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). The claim at issue in the appeal was limited to a microorganism modified to contain cDNA encoding human insulin. While the claim was largely characterized in structural terms, the single element of the claim, its modified cDNA, was described by what it *does* (encodes human insulin) rather than that it *was* (what chemical structures might do so). In invalidating this type of “single means” claim for lack of an adequate § 112(a) written description, the Federal Circuit relied on its own precedents explaining the impossibility that this type of functional protection could meet the statutory standard for a sufficient disclosure. See *Fiers v. Revel*, 984 F. 2d 1164, 1170 (Fed. Cir. 1993). “[A]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.”

First, while the Office is bound by Federal Circuit precedents interpreting the statutory requirements for *patentability*, it is no less tightly bound by the Supreme Court precedents that *deny patentability for functionally defined claims on § 112(a) disclosure insufficiency grounds*. Manifestly, the Office should not interpret Federal Circuit precedent as impeding its ability to follow Supreme Court dictates.

Second, while the presumptive applicability (or presumptive inapplicability) of § 112(f) under Federal Circuit precedents is of relevance to *claim construction for validity purposes*,²² the Federal Circuit itself has sanctioned a different approach to interpreting claims during patent examination in the Office. That different approach has an important policy objective that should not be neutered by blindly applying “presumptions” devised for a different purpose.

Specifically, with respect to the first consideration above, no *reasonable interpretation* of a claim should *presumptively disregard* § 112(f)’s applicability to a functionally defined claim if the claim otherwise would be categorically invalid under § 112(a). The Office should conclude that it would be *unreasonable* to do so. Nothing in extant judicial precedent would *require* the Office to examine claims under what the Office determined to be an unreasonable claim interpretation.

In the latter regard, the Office has a responsibility to accord claims being examined their “broadest reasonable interpretation.” The Supreme Court itself has explicitly sanctioned use of the BRI mechanism during patent examination—in order to encourage patent applicants to draft claims narrowly.²³ If *every reasonable interpretation* of the claim would result in the claim being narrowly confined as mandated under § 112(f), then according a claim its broadest *reasonable* interpretation must result in the application of § 112(f) to limit what the claim covers. Such a conclusion thereby avoids *an unreasonable interpretation of the claim* that would simply dictate unpatentability of the claim.²⁴

Thus, notwithstanding the extent that the Federal Circuit’s “presumptions” with respect to the applicability of § 112(f) must be applied to claim construction used for assessing validity in the courts (unless and until overruled by the court), *the Office need not apply those presumptions to the extent that they are inconsistent with the Office’s overarching responsibility to the public*

²² *Phillips v. AWH Corp.*, 415 F. 3d 1303 (Fed. Cir. 2005).

²³ See *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131, 2144-2145 (2016), “construing a patent claim according to its broadest reasonable interpretation helps to protect the public. A reasonable, *yet unlawfully broad claim* might discourage the use of the invention by a member of the public. Because an examiner’s ... use of the broadest reasonable interpretation standard increases the possibility that the examiner will find the claim too broad (and deny it), *use of that standard encourages the applicant to draft narrowly*. This helps ensure precision while avoiding overly broad claims, and thereby helps prevent a patent from tying up too much knowledge, while helping members of the public draw useful information from the disclosed invention and better understand the lawful limits of the claim. See § 112(a)...” [Emphasis added.]

²⁴ Given that the Office accepts the Supreme Court’s view that a remedial statute should be liberally construed to achieve its intended purpose, the Office would appear to be constrained to reject as unreasonable, even if possible, an invariably invalidating interpretation of a claim if the § 112(f) “safe harbor” could serve as a validity-preserving remedy. Only through broadly applying the remedial statute can the claim interpretation by the Office be assured of being a *reasonable* one.

to assess a claim's broadest reasonable interpretation—and do so in a manner consistent with the purpose of the BRI doctrine to encourage the patent applicant to draft claims narrowly.

All Functionally Defined Elements Of Independent Claims Should Be Presumed “Crucial”

Even if the Supreme Court's decision in *Halliburton* could be read as broadly condemning the functionally defined elements in valid combination claims, the Court's holding was limited to the unacceptable policy consequences of allowing functional characterizations to define the scope of protection at the most “crucial element” of the combination.²⁵ As noted above, this limited condemnation of functional language used to define claim elements stands in contrast to the *mandatory* provisions of § 112(f). On its face, § 112(f) applies to each functionally defined claim element, whether such element is determined to be a crucial one or not. All functional elements were declared by Congress to fall within the sweeping language under § 112(f).

In an examination context, the Office could take account of this discrepancy in various ways. One option available to the Office, however, could assure the greatest fidelity with the policy issues set out by the Supreme Court in *Halliburton*, given that the *Halliburton* holding is specific to the claim's *crucial* elements. Following this option, the revised guidance should specifically limit the direction to patent examiners to apply the new BRI guidance presumptively to the functionally defined limitations of *independent* claims.

Such a presumption would be fully aligned with good patent drafting practices that preferably confine independent claims to crucial claim elements. The most common—if not the best—claim drafting practice is to limit the nature and number of discrete elements present in independent claims to those that are essential for defining novel and non-obvious subject matter, *i.e.*, the claim elements that would be found to be crucial under *Halliburton*. Whenever such a claim-drafting practice is followed, it offers support for the presumption that each element is a crucial one in the manner that the Supreme Court described in *Halliburton*.

If the Office were to issue such guidance with respect to independent claims, examiners would not need to divert significant examination efforts to limitations appearing only in dependent claims that appeared to be functional nature. This distinction between functionally defined independent and dependent claims would reflect good patent policy since, once an independent claim has been found to be patentable, any functionally defined elements added via a dependent claim do not enlarge the protection to which the inventor is found to be entitled through the independent claim that the dependent claim references. In other words, since the functionally defined element of a dependent claim cannot enlarge the protection under a novel and non-obvious independent claim, the dependent claim's functional language cannot be objectionable under *Halliburton*'s rationale.

Thus, the Office might find it expedient in its guidance to instruct examiners that the “either/or” nature of § 112(f) applicability or § 112(a) *Halliburton*-dictated unpatentability specifically applies only to *independent* claims during examination. Such an interpretation would offer salutary consequences, including simplifying examination, encouraging the drafting

²⁵ *Halliburton*, *supra*, at 329 U.S. 9

of structurally limited independent claims that would appropriately define the legitimate scope of protection to which the inventor was entitled, and permitting an appropriate resort to functional claiming, *i.e.*, where additional limitations found only in dependent claims cannot result in functional claiming extending protection beyond the patent specification's disclosed embodiments.

Specifics For The Revised Principles For Incorporation Into Proposed § 112 Guidance

1. USPTO Examination Guidance Should Incorporate The Binary Outcome Of Either (1) § 112(f) Applicability Or (2) Invalidity Under Supreme Court Precedents, For Functionally Defined Independent Claims

As noted above, one thrust of the Office's proposed § 112 guidance looks to assist patent examiners in determining whether functional language appearing in claims should or should not trigger the applicability of § 112(f), in part by referencing the Federal Circuit's "presumption" based on whether the "magic" words "means for" appear in a functionally defined claim element.²⁶ However, again as noted above, the proposed guidance is silent on the *Halliburton*-imposed invalidity consequence if the functionally defined element in a claim that falls outside the invalidity "safe harbor" of § 112(f), *i.e.*, because either the Federal Circuit's presumption of inapplicability is not overcome when the "magic" words are absent from the claim or the Federal Circuit's presumption of applicability is overcome notwithstanding that the "magic" words "means for" are to be found in the claim element.

Rather than further perpetuate such presumption-borne machinations, new examiner guidance should be premised on the "either/or" consequence that results from an effort to claim an invention for which one or more crucial elements are defined in merely functional terms. For at least independent claims, each discrete element should be presumed to be crucial.²⁷ Either § 112(f) should protect such a claim from unpatentability under § 112(a), as lacking a sufficient disclosure, or the *Halliburton* holding requires that the claim be rejected or invalidated under § 112(a).

One way or the other, the Office's guidance to patent examiners should be direct, explicit, and categorical that no patentable claim can cover every means for carrying out a function in violation of the Supreme Court's holding in *Halliburton*—and the only protection against § 112(a) invalidity the statute provides for such a claim is to be found in the applicability

²⁶ "If a claim limitation recites a term and associated functional language, the examiner should determine whether the claim limitation invokes 35 U.S.C. § 112(f). Application of 35 U.S.C. § 112(f) is driven by the claim language, not by applicant's intent or mere statements to the contrary included in the specification or made during prosecution. Examiners will apply 35 U.S.C. § 112(f) to a claim limitation if it meets the 3-prong analysis set forth in the Manual of Patent Examining Procedure (9th ed. Rev. 08.2017, Jan. 2018) (referred to herein as 'MPEP'), § 2181, subsection I. At a high level, the 3-prong analysis includes evaluating whether: The claim limitation uses the term 'means' (or 'step') or a generic placeholder, the term is modified by functional language, and the term is not modified by sufficient structure, material or acts for performing the function." 84 Fed. Reg. 58.

²⁷ As noted in a footnote above, the Office may determine that such an "either/or" outcome should arise only in the case that an independent claim contains a functionally defined element—and do so on the basis that any functional language found only in a dependent claim does nothing to extend the scope of protection to which the patent applicant is entitled based on a structurally defined independent claim found to be novel and non-obvious.

of § 112(f) to limit the scope of such a claim to the corresponding structures, materials, or acts disclosed in the specification of the patent application.

2. Guidelines Should Make Effective Use Of The “Broadest Reasonable Interpretation” Mechanism During Examination To Force Applicants to Identify The Structures Limiting Valid Claims Having Functional Elements

As noted above, the Office has the responsibility to conduct the examination of the claims of a patent application by according each pending claim its “broadest reasonable interpretation.” This is recognized explicitly in the Office’s proposed guidance.²⁸

The BRI standard, however, does not entail affording pending claims their broadest *possible* interpretation. Indeed, the responsibility the Office has in interpreting claim language for the purpose of examination should reject any proposed interpretation that would be *unreasonable*, even if *possible*.

When claim elements are expressed in whole or in part in functional terms—without recitation of structures that serve to confine the scope of the limitation—the Supreme Court has been adamant that interpreting such claims to include *any means* for carrying out a recited function can render the supporting disclosure in the patent specification insufficient under § 112(a) to permit the claim to be found valid and enforceable. The decision of the Court in the *Halliburton* case explains that the most crucial elements of a claim to a combination, *e.g.*, the elements establishing the novelty/non-obviousness of the claim,²⁹ cannot be expressed in essentially functional terms because no patent specification can describe and enable every means for performing such a function, irrespective of what future technologies might be discovered and developed.

In light of the above predicates, the Office’s guidance on the examination of at least the independent claims containing such functionally defined elements should commence with a direction that the patent examiner recognize the necessity for confining claims to a broad, *but reasonable*, interpretation requires that the functionally defined elements will be construed as limited to the corresponding structures disclosed in the patent application’s specification and any equivalent structures. Specifically, the patent examiner should be directed to determine that the broadest *possible* interpretation of such a claim element, by potentially encompassing every means for performing the stated function, would be *unreasonable* in light of *Halliburton*.

²⁸ “One of the first steps in examining claims is determining the broadest reasonable interpretation (BRI) of the claim.” 84 Fed. Reg. 58.

²⁹ As noted above, while § 112(f) was drafted to apply to all claim elements, the policy justification for limiting what functionally defined claims may cover is triggered when *crucial* elements of a claimed combination are functionally defined. If the claim would meet the requirements for being novel and non-obvious if a particular element were excised from the claim, that excised element cannot constitute a crucial one under the rationale of *Halliburton*. Self-evidently, if the excised element were added back as a limitation in a claim dependent on the independent claim from which the element had been excised, the dependent claim could provide no greater scope of protection than the structurally defined independent claim would provide. Thus, meeting the cruciality standard under *Halliburton* requires a functionally defined element that contributes to the novelty of the combination.

Procedurally, patent examiners should be charged with undertaking a separate and distinct exercise, similar in purpose to the *Markman* process³⁰ that is often undertaken by the courts, under which the patent examiner would *formally assess* the BRI of the claims. This formal assessment would form a required predicate to addressing the substantive issues of patentability. Instead of a *Markman* hearing, the patent examiner could be directed to issue a formal “BRI Assessment” as a distinct section of the examiner’s first office action on the application’s patentability merits.

Such a “BRI Assessment” would identify for the patent applicant each limitation of at least each independent claim for which the broadest *reasonable* interpretation—on account of functional language—requires applying § 112(f) to the claim, so that the claim is *limited to the corresponding structures, materials, or acts disclosed in the patent specification and their equivalents*.³¹ The patent applicant, as part of responding to the “BRI Assessment” would be required either (1) to identify such corresponding structures to which the claim was being limited or (2) to demonstrate why such claim should not be found unpatentable based upon a lack of a sufficient disclosure under § 112(a), *e.g.*, the element would be understood by persons skilled in the art as limited to identifiable structures.

As indicated above, such a “BRI Assessment” would be premised on guidance stating that no reasonable interpretation of a functionally defined independent claim permits it to be construed except under the “safe harbor” of § 112(f). Otherwise, unpatentability would necessarily result under § 112(a) based on the *Halliburton* holding or based on § 112(b) (if the specification failed to disclose any specific structures, materials, or acts to which the claim must be limited).³² Such a premise is consistent with the Supreme Court’s articulated purpose for BRI, *i.e.*, *it encourages the applicant to draft narrowly*.

If the patent applicant failed to respond with an identification of the disclosed structures, materials, or acts to which the claim element would be limited—and the patent examiner found no merit in any alternative contentions by the patent applicant with respect to invalidity under *Halliburton* for lack of a sufficient disclosure—the patent examiner would then be positioned to issue a second and final action with respect to the § 112(a) or § 112(b) unpatentability of any such claims.³³

³⁰ *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). “Construction of the claims by the trial court is often conducted upon a preliminary evidentiary hearing, called a Markman hearing in homage to the [Markman] decision ... that established that this step must be performed by the judge, not the jury.” *EMI Group North America, Inc. v. Intel Corp.*, 157 F. 3d 887, 892 (Fed. Cir. 1998).

³¹ For claims for which no *Halliburton*-type issue appears to be present, the patent examiner would be positioned to simply examine such claims on their merits. The “BRI Assessment” would make no reference to such claims.

³² See the proposed guidance, *Indefiniteness under 35 U.S.C. § 112(b)*, at 84 Fed. Reg. 59.

³³ The revisions to the proposed guidance anticipate that patent examiners would issue a “BRI Assessment” with content along the following lines:

“Claim(s) _____ contain(s) one or more functionally defined elements (detailed below) that, absent the applicability of 35 U.S.C. § 112(f), would be broadly construed to cover subject matter extending beyond any structures, materials, or acts described in the specification for carrying out the function (or functions) stated in the claim(s). Such a broad interpretation, however, is not deemed by the Office to be a reasonable one in the context of patent examination, since it would result in one or more crucial elements of the claim lacking in an adequate written description under 35 U.S.C. § 112(a), thus rendering the claim unpatentable. See *Halliburton Oil Well Cementing*

If the Office were to implement the revised guidance to its patent examiners as outlined above for such claims containing functionally defined elements, the guidance would avoid the difficulties that arise once patents are issued and the courts are faced with resolving the “dueling presumptions” that the Federal Circuit has dictated must be used to determine the applicability of § 112(f) to limiting claim elements. Instead of this presumption-driven uncertainty, the patent prosecution record would be clear that claims that otherwise would have had a *Halliburton*-type validity defect would be limited to specific structures, materials, or acts specifically identified by the patent applicant during the patent examination process.

The BRI-related guidance for patent examiners would serve a second and potentially more important function. By addressing independent claims with functionally defined elements—and denying patents on those claims where the patent applicant did limit the claims to the specifically identified structures, materials, or acts disclosed in the patent specification—the above-proposed, BRI-infused, examination process would *preclude any possibility that claims so limited to the disclosed embodiments could more broadly preempt access to any abstract idea or other concept*.

Thus, the proposed “BRI Assessment” is intended to assert—in the patent examination context—the primacy of § 112(a) and § 112(f) in defining the scope of permitted protection accorded by a patent. Specifically, that primacy arises with respect to alternative inquiries of the same ilk, *including the issue of subject matter eligibility for patenting under Supreme Court precedents*.

Securing the primacy of the § 112 analysis during patent examination holds the promise of obviating most (perhaps all) of the need for examiners to apply the *Mayo/Alice* two-part test for limiting patent-eligible subject matter.³⁴ Particularly with respect to the question of whether a claim is directed to an “abstract idea,” the potential relevancy of the two-part test could be largely mooted if the Office were to strictly enforce the Supreme Court’s precedent on functional

Co. v. Walker, 329 U.S. 1 (1946) and *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010). Because, for the purpose of examining these claims, each such structurally defined element must be given its broadest reasonable interpretation, 35 U.S.C. § 112(f) applies in construing the claim(s). Each functionally defined element detailed below is, thus, to be considered as limited to cover only the corresponding structures, materials, or acts described in the specification for carrying out the stated function and their equivalents.

“Pursuant to § 112(f), the applicant is required to identify those structures, materials, or acts that are implicitly or explicitly described in the patent specification to which each of the respective functionally defined elements is to be limited. If the applicant fails to identify at least one such corresponding structure, material, or act for each functionally defined element in a claim, the claim will be subject to rejection under 35 U.S.C. § 112(b) as indefinite. See *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1381, (Fed. Cir. 1999).

“Alternatively, to the extent that the applicant regards any aspect of the examiner’s determination as being incorrect—and regards one or more claim elements detailed below as not being functionally defined—the applicant may traverse the determination to such extent. Such traverse must set forth the evidentiary basis on which a person skilled in the would understand that the putatively functional terminology in the claim nonetheless constitutes a description of identifiable structures, materials, or acts.

“The following claim elements have been determined to functionally define the element such that the broadest reasonable interpretation requires application of § 112(f) to their interpretation: _____.”

³⁴ See *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, *supra*, and *Alice Corp. v. CLS Bank International*, *supra*.

claiming, using its authority to invoke BRI as a basis for initiating patent examination of functionally defined claims in the manner outlined above.

3. The Office Should Refrain From Any “Implicit Exception” Analysis For Claims Subject To § 112(f)’s Limitation To Disclosed Embodiments In The Specification—Or For Claims Otherwise Found To Be Structurally Limited

The BRI-related guidance as discussed above, once carried out by patent examiners, would place the burden on patent applicants (1) to demonstrate the non-applicability of *Haliburton* to at least the application’s independent claims or (2) to concede that such claims fall within the embodiment-limiting § 112(f) “safe harbor.” Claims for which the *Halliburton* holding was demonstrated to be non-applicable would be those for which the claim terminology, while it may have initially appeared to the examiner to be functional in character, was established by the applicant to be confined to identifiable structures—as persons skilled in the art would understand such terminology to be so limited. Claims falling within the § 112(f) “safe harbor” would be limited to embodiments of the invention disclosed in the patent specification.

Either way, claims that are found to afford only such limited coverage following the proposed “BRI Assessment” cannot be regarded as directed to an “abstract idea,” one of the “implicit exceptions” to subject matter eligibility for patenting that the Supreme Court has indicated is to be determined under the *Mayo/Alice* two-part test. Such claims cannot preempt access to any idea or concept because the claims would be limited to the structures, materials, or acts that the inventor specifically set out in the patent’s specification or would otherwise be understood as so limited to structures by persons skilled in the art.³⁵

While the Office’s proposed guidance on subject matter eligibility notes that the examiner is not directed to examine for patentability in any particular order,³⁶ the use of the “BRI Assessment” at the time examination on the merits is initiated would provide the Office with the opportunity to defer examination with respect to the Supreme Court’s *Mayo/Alice* two-part test for subject matter eligibility for patenting while issues of patentability under 35 U.S.C. § 102, § 103, and § 112 were being addressed.

³⁵ See, generally, the amicus brief of Eli Lilly and Company, *et al.*, in support of the petition for certiorari in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F. 3d 1371 (Fed. Cir. 2015), rehearing en banc denied, 809 F. 3d 1282, available at <http://www.scotusblog.com/wp-content/uploads/2016/04/15-1182-Amicus-Brief-of-Eli-Lilly-et-al.pdf>. At p. 6, the petition notes:

[W]hile the Court’s jurisprudence assumes some overlap between the implicit exception and the statutory doctrines limiting patents, the Court has never considered whether the proper interpretation of the current statutory requirements, considered together rather than piecemeal, would fully address the policy considerations that caused the Court to mandate the non-statutory implicit exception. As detailed below, the explicit statutory requirements now present in the Patent Act, when properly interpreted and applied, bar securing valid patents that might prevent access to a law or product of nature, natural phenomenon, or abstract idea. For these reasons, it is now essential as an exercise of judicial restraint for the Court to consider whether to abrogate the implicit exception in deference to the present explicit statutory scheme.

³⁶ “Compact prosecution, however, does not mandate that the patentability requirements be analyzed in any particular order.” 84 Fed. Reg. 57.

Subject matter eligibility assessments under the Supreme Court’s precedents could be deferred until it is established whether the claimed invention (1) is limited under § 112(f) to disclosed structures, materials, or acts or (2) is alternatively limited to identifiable structures, notwithstanding that the claim language could otherwise have been construed as merely functional in character.³⁷ If either limitation were to apply to assure that the claimed invention is not to be broadly construed as setting out merely functionally defined elements, *i.e.*, is to be limited to identifiable structures, patent examiners should then be directed to conclude that the *Mayo/Alice* two-art test could be of no possible relevance.

On the other hand, should the patent applicant insist that § 112(f) is inapplicable—and the functionally defined elements of the claim entitle the inventor to cover all means to the functionally defined end, then—and only then—should the patent examiner examine the claims under the judicially imposed “implicit exception” through application of the *Mayo/Alice* analysis. Given that patent applicants will rarely, if ever, attempt to survive both the resulting *Halliburton*-based § 112(a) patentability challenge to such functionally defined claims, as well as the *Mayo/Alice* two-part test for abstractness, the Office’s guidance to examiners reserving the *Mayo/Alice* analysis to these highly unlikely circumstances would not materially detract from the Office’s objective of securing compact prosecution of patent applications.

³⁷ The applicability of § 112(f)—to defeat patent drafting efforts that might otherwise secure patent protection extending to the idea or concept on which an invention is based—does not address all of the subject matter that the Supreme Court has declared to be an “implicit exception” to the subject matter that is to be regarded as eligible for patenting. Specifically, it does not address efforts to secure a patent directed to a law/product of nature or natural/physical phenomenon. The Office might consider issuing further guidance that could fill this lacuna. Such further guidance could focus on the issue of “inherent anticipation” under 35 U.S.C. § 102. The additional guidance might supersede reliance on subject matter eligibility as a means of limiting the availability of valid patent protection on inventions arising from nature. In this regard, the statutory novelty requirement bars the patenting of any subject matter that exists or operates in nature. In *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889), the Supreme Court described the application of the “inherent anticipation” aspect of the novelty requirement by concisely stating “[t]hat which infringes, if later, would anticipate, if earlier.” For the purpose of applying “inherent anticipation” principles, it matters not whether a natural law or product or natural phenomenon was newly-discovered. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003), *reh’g en banc denied*, 348 F.3d 992 (Fed. Cir. 2003). All such naturally-occurring subject matter necessarily exists prior to its discovery, thereby precluding the possibility that it could be validly patented. Thus, any allegation that a law or product or phenomenon might infringe a patent claim would establish that the claim was anticipated under § 102. As such, the *inherent anticipation* doctrine prevents validly patenting any law or product of nature or natural phenomenon, even if newly-discovered. In a similar manner, the “inherent anticipation” doctrine applies to patents with claims drafted in terms that are broad enough to preempt access to the natural law or product or phenomenon. This result is dictated by the rule that even if only one specific embodiment (*i.e.*, a species) falling within the scope of a claim was previously known or inherently existed, the species defeats novelty for the entire claim, *e.g.*, see *In re Slayter*, 276 F.2d 408, 411 (C.C.P.A. 1960) (stating that “[i]t is well settled that a generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus . . .”). Thus, any effort to draft a patent claim that would extend protection under a patent to preempt access to any natural product or law or natural phenomenon should inherently fail the novelty condition for patentability under § 102, thereby precluding any need to resort to the “implicit exception” relating to a law/product of nature or natural/physical phenomenon. Such would merely duplicate what the patent statute’s novelty requirement inherently excludes from protection.

Conclusions

The Office's two recent guidance documents, while treating § 112 disclosure sufficiency and patent eligibility under recent Supreme Court precedents as separate topics, deal with the same overarching principle. The principle is a simple, non-controversial one: valid patents should cover only what the disclosed invention is shown to be through the patent specification itself—and not more broadly protect the concepts or ideas on which the invention was based.

The proposed § 112 guidance should be revised to more fully embrace the inseparability in purpose between disclosure sufficiency and subject matter eligibility. It should do so by guiding examiners towards a more rigorous examination with respect to the former in a manner that reduces the latter to at most near irrelevance.

In order to do so, the revisions suggested for the proposed § 112 guidance require a fundamental rethinking of the obligation of the Office to examine patent application claims under the BRI standard. This rethinking should apply particularly to independent claims that define the fullest breadth of protection that a patent applicant will secure.

If the Office concludes that the broadest *reasonable* interpretation of a claim must be distinct from the claim's broadest *possible* interpretation, it opens the door to interpreting all claims, most particularly all independent claims, appearing to have functionally defined elements as subject to § 112(f)'s limitations on coverage. This limitation should apply irrespective of whether or not such claims would be presumed subject to § 112(f) under Federal Circuit precedents (or presumed not to be so subject).

Once patent examiners are obliged to so construe claims, a further opportunity is created to require patent applicants either (1) to identify the corresponding structures, materials, or acts to which the claim will be limited or (2) to demonstrate that the putatively functionally defined elements reference structures—as such elements would be understood by persons skilled in the art. No other path would be open to patent applicants under which clever claim drafting would afford a route of escape from the Supreme Court's holding in *Halliburton*.

The upshot of the suggested revisions to the Office's proposed guidance is, thus, that § 112(a) and § 112(f) would do the heavy lifting in terms of barring claims directed to “abstract ideas” or other generalized concepts. Indeed, if the Office were to implement these suggested revisions, it is possible that—in actual practice—the guidance so promulgated may do all the lifting needed to bar conceptual claims of the type that the Supreme Court has repeatedly said cannot be validly patented.

If so, the revised guidance proposed here may assist in eventually ending the nightmare of the Supreme Court's arbitrary and essential unworkable standard for assessing patent eligibility under the *Mayo/Alice* two-part test. This arbitrary standard, operating today to invalidate all manner of claims as patent ineligible, would give way to appropriately limiting patent claims to cover all that the inventor disclosed—and, self-evidently, what the inventor should be entitled to validly patent once found by the Office to be novel, useful, and non-obvious.