

**RESPONSE TO THE OCTOBER 17, 2016 FEDERAL REGISTER NOTICE<sup>1</sup>**  
**ON PATENT SUBJECT MATTER ELIGIBILITY:**  
***EXPLORING THE LEGAL CONTOURS OF SUBJECT MATTER ELIGIBILITY***  
**ROUNDTABLE 2, DECEMBER 5, 2016 – STANFORD, CA**

ROBERT A. ARMITAGE – CONSULTANT, IP STRATEGY & POLICY

Michelle K. Lee, Undersecretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, Alexandria, VA 22313-1450

Undersecretary Lee:

Thank you for the opportunity to provide comments relating to the legal contours of subject matter eligibility in the U.S. patent system.<sup>2</sup> The comments offered below have been developed pursuant to work undertaken over the past two years attempting to better understand this issue.

These efforts have included presentations made before various patent-focused groups and participation on various task forces examining possible legislative options to address patent eligibility issues.<sup>3</sup> In addition, these activities include serving as lead counsel for five amici supporting the grant of certiorari on the issue of patent eligibility in the *Sequenom* appeal.<sup>4</sup>

The comments below offer both a general commentary addressing the current state of U.S. patent eligibility law and a specific proposal<sup>5</sup> for addressing the issues this law presents through legislation. This submission is offered in the hope that it might assist in reaching a consensus on an amendment to the patent laws that would overrule the recent jurisprudence of the United States Supreme Court on the issue of subject matter eligibility for patenting.<sup>6</sup>

Creating such a consensus is a critical predicate to opening a path for Congress to enact legislation that is much needed for the good of the patent system. The comments below are grounded on the belief that the overarching objective of such legislation should be to abrogate

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<sup>1</sup> Fed. Reg. 81:71485-89 (Oct. 17, 2016)

<sup>2</sup> “The USPTO is also interested in facilitating a discussion among members of the public regarding the legal contours of eligible subject matter in the U.S. patent system.” *Id.* at p. 71485.

<sup>3</sup> As a result of these efforts, my views on an appropriate legislative response to § 101 issues have evolved dramatically over time. See “A Two-Pronged Approach To Addressing § 101’s Judicially Imposed “Implicit Exceptions” To Eligibility For Patenting: A Path Forward For Judicially Retiring These Exceptions And A Legislative Proposal As An Alternative Means To The Same End,” Naples Roundtable 2016, (available at <https://www.thenaplesroundtable.org/wp-content/uploads/2015/09/A-New-Approach-to-Superseding-Implicit-Exceptions-to-Patent-Eligibility-by-Robert-A.-Armitage.pdf>).

<sup>4</sup> *Sequenom, Inc. v. Ariosa Diagnostics, Inc., et al.*, App. No. 15-1182, *cert. den.*, June 27, 2016, [https://www.supremecourt.gov/orders/courtorders/062716zor\\_4fbi.pdf](https://www.supremecourt.gov/orders/courtorders/062716zor_4fbi.pdf).

<sup>5</sup> These comments in this submission are a response to the specific request at 81 Fed. Reg. 71487, “the USPTO would appreciate comments on whether legislative changes are desirable and, if so, views on the elements of such changes.”

<sup>6</sup> See *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 Supreme Court’s “implicit exception”<sup>7</sup> to the statutory requirements defining subject matter eligibility for patenting, as well to overrule the two-part test<sup>8</sup> dictated by the Court for implementing it.

## *Introduction and Background*

### **The Case for Legislative Intervention and Its Ripeness**

The necessity—even urgency—of proceeding with a legislative response to overrule the non-statutory aspects of the Supreme Court’s patent-eligibility jurisprudence arises in part from the recent decision of the Court denying certiorari in the *Sequenom* appeal. The Court declined to hear this appeal notwithstanding a compelling case for granting certiorari that was set out in more than a score of amicus briefs supporting the petitioner.<sup>9</sup> These *amici* laid out in convincing detail an array of arguments supporting the grant of the petition. The *amici* were unanimous that the Court should retreat from its recent eligibility holdings—at least as they were applied in *Sequenom*—and reconsider the wisdom of its two-part test for implementing the implicit exception.

Surprisingly to many critics of the Court’s jurisprudence, the Supreme Court declined to hear the appeal. What critics found equally unsettling was the apparent ease with which the Court dismissed the petition. It made no effort to seek the Solicitor General’s counsel before doing so. In light of the *Sequenom* facts (*i.e.*, uniquely among the industrialized countries, the claimed invention in *Sequenom* was found patent-ineligible), this appeal would have been a near-ideal vehicle for the Court to consider—and possible self-correct—its jurisprudence.

On the facts in *Sequenom*, the Court would have been obliged to consider how arbitrary the application of the two-part test can be when applied in practice. Equally significantly, this petition offered an opportunity for the Court to recognize how distantly U.S. patent-eligibility law has strayed from accepted international norms among industrialized countries for determining patent eligibility.

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<sup>7</sup> The “implicit exception,” discussed further below, purports to bar the ability to patent a natural law or phenomenon or other abstract concept. “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.” *Alice v. CLS Bank* at 134 S. Ct. 2354.

<sup>8</sup> The reference to the “two-part test,” again discussed further below, is also commonly referenced as the *Mayo/Alice* test because its parameters were derived from recent Supreme Court decisions barring patents on subject matter eligibility grounds. “In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012), we 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.’” Quotation from *Alice v. CLS Bank* at 134 S. Ct. 2355.

<sup>9</sup> Copies of the 22 briefs supporting the grant of certiorari are available at <http://www.scotusblog.com/case-files/cases/sequenom-inc-v-ariosa-diagnostics-inc/>.

Given the posture of the Sequenom petition, especially in light of the amicus support it attracted, the Court’s decision to decline to judicially revisit the issue of subject matter eligibility suggests that no near-term likelihood exists that the Supreme Court will reconsider its directives to the lower courts on the question of subject matter eligibility for patenting. As a consequence, an exploration of legislation options for redress is now ripe.

### **Abrogation: The Optimal Resolution If the Supreme Court Reengages on Eligibility**

The present submission is principally focused on possible legislative efforts to address the issue of patent eligibility. To the extent, however, that judicial opportunities were to arise to address the eligibility issue, it is worthwhile exploring at the outset what an optimal resolution by the Courts might look like and, more importantly, the constitutional and policy arguments that would underpin such a resolution in the courts.

Appendix B of this submission provides excerpts from the amicus brief of Eli Lilly and Company, *et al.* in support of the Sequenom certiorari petition.<sup>10</sup> It argues for a simple abrogation of the implicit exception and the two-part test implementing it.

If a near-term judicial resolution of the issues relating to subject matter eligibility for patenting were possible, such a resolution would ideally be the naked abrogation of the non-statutory eligibility requirements that the Supreme Court has set out—as urged in the Lilly, *et al.*, brief. It would take the form of the Supreme Court doing no more than simply abrogating its “implicit exception” jurisprudence *in toto*—without articulating any substitute non-statutory limitations on inventions eligible for patenting

Convincing the Court to recant what it has characterized as 150 years<sup>11</sup> of consistent jurisprudence would be a tall order. However, given where the Court has positioned eligibility law, it is a challenge that should be joined.

There is good reason—and good reasoning—for why the Court should simply abrogate. As the Lilly, *et al.* brief lays out through a set of extensive arguments, the patent statute contains *explicit* provisions that bar patents on a natural law or phenomenon or other abstract concepts. Explicit statutory provisions also operate to frustrate the use patent drafting techniques to end-run the statutory bar on patenting any form of abstract concept.

Such statutory limitations demolish the sole rationale the Court has used to justify acting outside the explicit statutory provisions of the patent law. Specifically, they refute the Court’s errant view the patent statute itself otherwise would fail to preclude the issuance of valid patent claims for subject matter that can dominate, preempt, or otherwise preclude access to any abstract concepts on which a claimed invention is based or to which it otherwise relates.

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<sup>10</sup> The complete brief as filed is available at <http://www.scotusblog.com/wp-content/uploads/2016/04/15-1182-Amicus-Brief-of-Eli-Lilly-et-al..pdf>.

<sup>11</sup> “We have interpreted § 101 and its predecessors in light of this [implicit] exception for more than 150 years.” *Alice v. CLS Bank* at 134 S. Ct. 2354.

The Lilly, *et al. amici* were far from alone in making these and similar arguments that the Supreme Court’s “implicit exception” jurisprudence and the two-part test that implements it are entirely unnecessary. A variety of learned commentators have persuasively advocated for such an abrogation.<sup>12</sup>

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<sup>12</sup> See especially, Bruce Sunstein, *How Prometheus Has Upended Patent Eligibility: An Anatomy of CLS Bank v. Alice Corp.*, 49 New England Law Review 1, 38 (2015), available at <http://sunsteinlaw.com/wp/wp-content/uploads/2015/05/Sunstein-How-Prometheus-Has-Upended-Patent-Eligibility.pdf>, proposing a straightforward abrogation of the Supreme Court’s “implicit exception” jurisprudence.

In addition, see Professor Michael Risch, *Everything is Patentable*, Tennessee Law Review Vol. 75:591-658 (2008) (available at [http://works.bepress.com/michael\\_risch/3/](http://works.bepress.com/michael_risch/3/)), in which Professor Risch concludes at pp. 657-658:

Abandoning judicial subject matter restrictions will not answer all of the difficult patentability questions that have arisen and may yet arise as our nation’s inventors and researchers continue to discover new technologies. Those difficult questions, however, should be answered by the general criteria that Congress has established—criteria that have worked for over 150 years—to determine whether a particular patent claim should be allowed.

The exact contour of the trade-offs between innovation and patent protection are largely unknown. Therefore, the PTO and courts should focus on answering specific questions about how to best apply rigorous standards of novelty, nonobviousness, utility, and specification with a scalpel rather than simply eliminating broad swaths of innovation with a machete.

Scholarship leading to a similar conclusion also comes from Professors Lefstin and Menell. In the Lefstin-Menell *Sequenom* amicus brief supporting the grant of certiorari in *Sequenom* (available at <http://www.scotusblog.com/wp-content/uploads/2016/04/SSRN-id2767904.pdf>), pp. 25-26, they note:

Overly broad and abstract claims pose problems for the patent system, particularly if patents are not restricted to the technological arts. . . . But the proper response is not to rewrite § 101 by judicial fiat to include a double requirement of inventive discovery *and* inventive application, but to ensure that the doctrines specified by Congress are implemented with appropriate rigor – as this Court has done for the non-obviousness requirement of § 103 in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), and for the claim definiteness requirement of § 112(b) in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014). Nor has the Federal Circuit been idle. In *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc), the court confirmed a separate written description requirement under § 112(a), rendering invalid any patent that attempts to claim a new scientific discovery without disclosing a specific and concrete means of application. And in *Williamson v. Citrix Online, LLC*, 792 F.3d 1339 (Fed. Cir. 2015) (en banc), the Federal Circuit tightened the standards for functional claiming under § 112(f), ensuring that patents employing broad functional claiming without corresponding disclosure of structure are indefinite under § 112(b).

These doctrines may require fact-intensive inquiries into such matters as the state of the prior art, the capabilities of skilled artisans, and the claim scope permissible based on the specification. But that is the structure Congress established under the 1952 Act. The judicial branch may not discard that statutory framework in favor of an “I-know-it-when-I-see-it” standard for patentability under § 101.

In a nutshell, the common theme of this league of abrogationists is that the Supreme Court’s policy justification for the imposition of the “implicit exception”—a concern that valid patents could preclude access to the basic tools of science and technology and thereby impede progress in the useful arts in contravention of the constitutional justification for creating a patent system—is fully addressed through other statutory requirements for patentability.

Thus, for the believers in the merits of this approach, the outright abrogation of this jurisprudence by the Court cannot possibly raise serious constitutional or insuperable patent policy concerns—and would well serve the interests of the innovation by assuring that patents would be available and enforceable across all fields of technology, without limitation, restriction, or discrimination. If getting the Court itself to abrogate its own precedents is a tall order, proponents of abrogation believe—and have thoroughly demonstrated through their advocacy—that arguments for doing so stand even taller.

### **The Rationale for Creating “Abrogation-Plus” Approaches to Addressing Eligibility**

Efforts are now ongoing to seek congressional action on the issue of the Supreme Court’s § 101 jurisprudence, given that it now appears the Court will not do so over any near-term horizon. A successful resolution of this issue by Congress requires a consideration of more variables than would need to be addressed in the case of a judicial overruling of errant precedents. It does not follow, therefore, that the optimal resolution by the courts would necessarily constitute a feasible legislative approach.

Remedial action by the courts is first and foremost based on a consideration of the legal merits of the proposition placed before the court. Action by Congress typically takes account of an array of considerations—and the optimal legal path forward to resolution by the courts is not necessarily a politically viable one in the legislature.

Based upon discussions over the past two years, especially among members of the patent bar, it appears unlikely that the needed coalition could be formed to urge Congress to act to simply abrogate of the Supreme Court’s “implicit exception” jurisprudence as argued in the Lilly, *et al.* amicus brief.<sup>13</sup> A belief among a substantial segments of the patent community is that legislating a Lilly-type abrogation, were it to be accomplished at all, would need to be accompanied by new and concomitantly imposed statutory limitations on subject matter eligible for patenting.

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Lastly see *Dave Kappos Calls for Abolition of Section 101*, *The National Law Review*, April 14, 2016 (available at <http://www.natlawreview.com/article/dave-kappos-calls-abolition-section-101>), in which former Undersecretary Kappos is quoted as urging that “It’s time to abolish [the Supreme Court’s “implicit exception” jurisprudence under] Section 101, and the reason I say that is that Europe doesn’t have 101 and Asia doesn’t have 101 and they seem to be doing just fine in constraining patent-eligible subject matter.”

<sup>13</sup> The naked abrogation approach has been politely ridiculed as being politically naïve by a sufficient number of respected elements within the patent bar that its present political non-viability in Congress has become a self-fulfilling prophecy. Ultimately, the lack of interest—much less consensus—within substantial segments of the patent bar on the merits of a legislative enterprise aimed at a naked abrogation of the implicit exception suggests that it would be neither productive (nor even constructive) in the near term to pursue the legislative repeal of the implicit exception by itself.

As a consequence, this political infirmity has led to a quest for alternative proposals on which a broader consensus could be developed both as to their possible merit and, just as importantly, as to their potential political viability.

To construct such proposals, efforts have been ongoing in multiple forums within the patent community to identify new statutory formulations for limitations on patentability that might take the place of two-part test used by the courts to implement the implicit exception. The discussion below attempts to contribute to this effort by addressing various types of new statutory requirements limiting patent eligibility that might be devised, as well as the specific form that one such approach might take.

These proposals, irrespective of source, all share a common feature. They operate by superseding Supreme Court’s *implicit* jurisprudence through the enactment of new and *explicit* statutory patent-eligibility requirements. The inclusion of *replacement* patent-eligibility limitations is seen as the key to the political viability of these *abrogation-plus* approaches.

### ***The Scope of the Problems Arising from the “Implicit Exception” and Its Two-Part Test***

Any examination of the parameters for a legislative effort at remediating patent-eligibility law should be grounded on a complete understanding of what has gone wrong with the existing judge-made law and why. Such an understanding is helpful to assure any remedy is root-cause-based and commensurate in scope with the nature of the problems presented to the patent system.

### **The Pernicious Effects of the Two-Part Test’s Subjective and Arbitrary Character**

Critics of the Supreme Court’s § 101 jurisprudence charge that the present law on “subject matter eligibility” has become unjustifiably punitive during the past decade. In addition, as the decision to proceed with Roundtable I on USPTO Subject Matter Guidelines suggests,<sup>14</sup> the current judge-made law on patent-eligibility is at the very least not readily administrable by the Office. As will be detailed below, such charges and difficulties arise in part because the two-part test is both subjective and arbitrary in its application.

As a consequence, the implicit exception—and particularly its implementing two-part test—compromise the ability of U.S. patents to operate as effective property rights, rights capable of reliably supporting investment in the development and commercialization of important new invention across all fields of technology. Moreover, this judicial contradiction of the statutory patentability requirements operates as an unearned bonanza for those seeking to summarily evade otherwise valid patents on novel, useful, and non-obvious technology—technology that has been discovered and developed for commercialization often at great risk and great expense by its creators.

As noted above, the domestic law on patent eligibility has wandered far outside the established international norms for patent eligibility among industrialized countries. Patent

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<sup>14</sup> Roundtable 1, USPTO Guidelines on Subject Matter Eligibility, seeking “[s]uggestions to how to improve the Office’s subject matter eligibility guidance . . . .” 81 Fed. Reg. at 71487.

eligibility determinations in the United States require the application of principles and standards that are unknown outside the United States.

This has resulted in subject matter that is readily patentable outside the United States failing to meet the idiosyncratic domestic approach to determining patent eligibility. As noted by respected international commentators, the *Sequenom* claims represent a “poster child” for the oversized domestic patent-eligibility standards.<sup>15</sup>

Moreover, the problematic nature of this jurisprudence is compounded because the Supreme Court has stated that § 101 eligibility can be assessed in isolation, as a *threshold determination*,<sup>16</sup> before any other patentability requirements are considered. In this manner, the two-art test is routinely applied to inventions that would be unpatentable, in any event, on other statutory grounds.

The isolation and prioritization of patent eligibility determinations—particularly as applied to otherwise “bad” patent claims—has had the perverse effect of producing a self-reinforcing bloating of § 101 unpatentability determinations. Courts are motivated by nothing more than human nature to stretch the implicit exception to summarily validate claims that would be invalid for other reasons.

By *stretching* of the threshold eligibility determination to ensnare an otherwise invalid claim, the stretched doctrine then becomes a menace when its outsized form is later applied to meritorious patent claims. This phenomenon was almost certainly at play when the *stretched* law arising from the peculiar claims in *Mayo v. Prometheus* was applied to what should have been straightforwardly valid claims in *Sequenom*.<sup>17</sup>

### **The Breadth of the Bar to Eligibility Is Unwarranted Given Its Scant Rationale**

The implicit exception nominally dictates that a claimed invention in a patent or patent application is ineligible for patenting if the subject matter being claimed is a natural law or phenomenon or other abstract concept. Were it rigorously restricted to such laws, phenomena, or

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<sup>15</sup> See the amicus brief of the Institute of Professional Representatives Before the European Patent Office, specifically criticizing the Federal Circuit’s application of the two-part test in the *Sequenom* appeal (available at <http://www.scotusblog.com/wp-content/uploads/2016/04/15-1182-ac-Institute-of-Professional-Representatives-Before-the-Europe....pdf>).

<sup>16</sup> “Section 101 imposes a threshold condition. ‘[N]o patent is available for a discovery, however useful, novel, and nonobvious, unless it falls within one of the express categories of patentable subject matter.’” *Bilski v. Kappos* at 130 S. Ct. 3236 (2010).

<sup>17</sup> Perhaps the prototype for bad patent claims producing bad patent eligibility law is *Mayo v. Prometheus*. *Prometheus* secured a patent a two-step claim with two “wherein” clauses that should have been as manifestly patent-eligible as the claim was manifestly unpatentable otherwise. Looking at patent eligibility of this claim in isolation led to a contrived construction of the claim that foretold its ineligibility. See Robert A. Armitage, *Perspectives: A Prometheus, Playing with Fire, Gets Burned*, ABA Intellectual Property Law Section, Landslide Magazine, Vol. 4, Issue 6 (July/August 2012) (available at [http://www.americanbar.org/content/dam/aba/publications/landslide/landslide\\_august\\_2012/armitage\\_landslide\\_july\\_august\\_2012.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/publications/landslide/landslide_august_2012/armitage_landslide_july_august_2012.authcheckdam.pdf)).

concepts themselves, the doctrine might be no more than benignly redundant to other statutory patentability requirements that would in any event bar the patenting of such subject matter.<sup>18</sup>

However, under recent Supreme Court jurisprudence, the standard used for assessing whether such an abstract concept is being claimed is not a *per se* standard, but extends to any subject matter ensnared under the two-prong test. As noted earlier, the two-prong test first looks to whether the claimed invention is somehow *directed to* an abstract concept and, if so, then determines whether the invention as claimed adds *significantly more* to the concept—either through the claim’s individual elements or as an ordered combination—such that an *inventive concept* is present in what is claimed.

This test opens the door to a wide-ranging application to inventions that are neither a law nor a phenomenon nor an idea nor any other abstract concept. For a court to justify imposing such a free-ranging judicial bar contradicting the statutorily mandated outcome on patentability, the rationale for doing so should be as extensive as the judicially imposed bar is potentially sweeping. It is not.

The core of the Court’s rationale for the two-part test is no more than an unsubstantiated conjecture. The Court’s core premise for promulgating this test is that patent drafting techniques exist that, unless somehow neutered, would permit a draftsman to circumvent a bar restricted to abstract concepts themselves.<sup>19</sup>

However, the Court has never undertaken a full analysis of whether its conjecture with respect to draftsmanship circumvention is at all possible. In particular, it has never examined in any detail whether the patent statute, taken in the aggregate, imposes sufficient statutory requirements for securing a valid claim so as to entirely frustrate efforts to secure patents capable of covering or even preempting abstract concepts.<sup>20</sup> As discussed below, it clearly does.

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<sup>18</sup> The nature and comprehensiveness of this redundancy is addressed *infra*.

<sup>19</sup> The Court has observed that a mechanism is needed that is able to “provide practical assurance that the [claimed invention] is more than a drafting effort designed to monopolize [an abstract concept] itself.” *Mayo v. Prometheus* at 132 S. Ct. 1297; see also *Alice v. CLS Bank* at 134 S. Ct. 2358-359, warning against making “the determination of patent eligibility depend simply on the draftsman’s art.” (internal quotation marks omitted).

<sup>20</sup> The Court started down this path in *Mayo v. Prometheus*, but then ended the journey after taking only a few baby steps. In *Mayo v. Prometheus*, the Solicitor General had urged that “other statutory provisions—those that insist that a claimed process be novel, 35 U.S.C. § 102, that it not be ‘obvious in light of prior art,’ § 103, and that it be ‘full[y], clear[ly], concise[ly], and exact[ly]’ described, § 112—can perform this screening function.” The Court, in an inexplicable rejoinder, rejects that other statutory provisions can screen out claims directed to abstract concepts, noting: “This approach, however, would make the ‘law of nature’ exception to § 101 patentability a dead letter. The approach is therefore not consistent with prior law. The relevant cases rest their holdings upon section 101, not later sections.” In effect, the Court simply refused to address the merits of the Solicitor General’s argument that the *substance* of the remaining sections of the patent law addressing patentability mooted altogether the need for a § 101 implicit exception do to so in a redundant manner. The Court continued with a set of contentions that were equally mystifying: “We recognize that, in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap. But that need not always be so. And to shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.” In effect, the Court simply refused to examine whether § 102 *inherently* precludes the patenting of a natural law or phenomenon because—by definition—they *inherently* exist prior to their discovery and, therefore, cannot be new even if newly discovered. Other Supreme Court precedents, discussed *infra*, hold as much. The “greater legal uncertainty”

Further, neither the *directed to* nor the *significantly more* aspects of the two-art test—given its relative recent articulation—has ever been the subject of an after-action review by the Court. Having declined to see its handiwork in operation in *Sequenom*, the Court has yet to come to grips with how well the test is living up to the Court’s expectations for it.

It is possible, therefore, that the Court could simply view its work as unintentionally Frankensteinian—that it is too arbitrary and, therefore, too easy for any sort of invention to come within its grasp.

As one example, the Court has never been challenged to explain how—if a valid patent claim that is determined to be directed to an abstract concept under the two-part test—the required “inventive concept” differs from the otherwise required *inventiveness* under 35 U.S.C. § 103. The Court has essentially offered no policy guidance on what is required to navigate in the real world between § 101 and § 103, between these non-statutory and statutory inventiveness requirements.

Absent the use of the two-part test, the Court has posited that valid patent claims, even if nominally expressed in terms of a process, machine, manufacture, or composition of matter, could nonetheless otherwise be crafted in such a conceptual manner so as to *preempt* an abstract concept,<sup>21</sup> thereby allowing the claim to be enforced in such a manner as to prevent access to basic tools of science and technology,<sup>22</sup> e.g., as embodied in a natural law or phenomenon or other abstract concept.

Doing so, according to the Court, could be inconsistent with the constitutional mission of the patent system to promote progress in the useful arts.

However a sequential analysis of the Court’s statement of the implicit exception, the Court’s rationale for imposing the two-part test to implement it, and then the actual operation this test itself *exposes the flaws in judicial edict*. Even if some non-statutory intervention in the patent law could be credibly justified by the Court, its current jurisprudence hardly qualifies as an acceptable judicial standard.

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observation is made without any consideration of devastating arbitrariness of the implicit § 101 test that the Court dictated must be used in place of long and well-settled statutory provisions. While the Court contends that other statutory sections are not equipped to ferret out abstract concepts from patentable subject matter, its explanation disregarded its own precedents. If a component of a claim is a “law of nature,” that component of the claim cannot be treated as novel under the Court’s own precedents—what is otherwise old does not become new simply because other aspects of what is claimed are in fact novel. The Court concludes by noting the shortcomings that it found in § 102 being up to the task of precluding valid patent claims directed to abstract concepts applied to § 112 as well. However, the Court, again without citing its own contrary precedents as discussed *infra*, found § 112 wanting, “These considerations lead us to decline the Government’s invitation to substitute §§ 102, 103, and 112 inquiries for the better established inquiry under § 101.” Once the Court Court addresses the actual substance of the § 102, § 103, and § 112 requirements—as interpreted under the Court’s own precedents—there is good reason to believe that the Court itself would not find its *dicta* in *Mayo v. Prometheus* controlling.

<sup>21</sup> “[T]he Court’s precedents . . . warn us against upholding patents that claim processes that too broadly preempt the use of a natural law.” *Id.* at 132 S. Ct. 1294.

<sup>22</sup> “[M]onopolization of [the basic tools of scientific and technological work] through the grant of a patent might tend to impede innovation more than it would tend to promote it.” *Id.* at 1293

*An “Implicit Exception” is Unnecessary to Barring Patents Directed to Concepts*

First, as to the statement of implicit exception itself, the exception on its face purports to set out an *implicit bar* on patent eligibility restricted to subject matter for which Congress imposed *explicit bars* to the patenting of such subject matter under statutory requirements for patentability.

Neither laws nor products of nature can be validly patented under the explicit requirements in the patent statute; the same applies to natural or physical phenomena.<sup>23</sup> Likewise no idea itself, whether or not abstract, can meet the statutory requirements for patenting.<sup>24</sup>

The patent statute itself—irrespective of the Court’s “implicit exception” jurisprudence—would never permit valid patent claims to be issued on such conceptual subject matter. Valid patent claims must be expressed as a “process, machine, manufacture, or composition of matter.” Statutorily eligible subject matter cannot be a concept; it must be a *physical* product or process.<sup>25</sup> By statute, valid patent claims must be confined to embodiments or applications, not the ideas or concepts that might undergird them.

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<sup>23</sup> The statutory novelty requirement under 35 U.S.C. § 102 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 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.” The Federal Circuit restated the above rubric as “[t]hat which would literally infringe if later in time anticipates if earlier than the date of invention.” *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988). For the purpose of applying “inherent anticipation” principles, it matters not whether a natural law or product or natural phenomenon was newly-discovered. See *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) (stating that “recognition by a person of ordinary skill in the art . . . is not required to show anticipation by inherency.”).

<sup>24</sup> These four statutory categories to which valid patent claims are limited under § 101 (*i.e.*, a “process, machine, manufacture, or composition of matter”) force valid patent claims to be expressed in terms of the *applications* that *physically embody* an invention. As such, they represent subject matter that is mutually exclusive with respect to mere concepts—such as laws, phenomena, and ideas. Therefore, the *explicit* § 101 requirement that claims be directed to a statutory category excludes any possibility for securing a valid patent for an associated concept rather than for its embodiments/applications.

<sup>25</sup> A “process” under § 101 requires no less physicality than a “product.” As applied to patenting, the earliest definition of the statutory term “process” offered in a decision of the Supreme Court set out a like notion of non-conceptual physicality—“[a] process is a mode of treatment of certain materials to produce a given result. It is an *act*, or a *series of acts*, performed upon the subject-matter to be transformed and reduced to a different state or thing.” 12F *Cochrane v. Deener*, 94 U.S. 780, 788 (1877) (emphasis added). The *act* or *acts* constituting a “process” under the patent law were, thus, of a like physical nature to the other statutory categories. “The process requires that certain things should be done with certain substances, and in a certain order . . . .” *Ibid.*; see also *Tilghman v. Proctor*, 102 U.S. 707, 728 (1881) (stating that “[a] machine is a thing. A process is an *act*, or a *mode of acting*. The one is visible to the eye, — an object of perpetual observation. The other is a conception of the mind, *seen only by its effects* when being *executed or performed*.” (emphasis added)). Thus, to carry out a process under the patent laws means carrying out one or more *acts* that are the *physical embodiment(s)* of any idea or concept to which a process invention relates.

*Statutory Requirements Demanding “Sufficiency of Disclosure” Bar Patents That Would Otherwise Preempt Underlying Concepts*

The Court’s rationale for imposing the “implicit exception” essentially concedes the point that the judicial mission of the exception exceeds a simple bar to patents on laws, phenomena, and other concepts themselves, as does the need for and the content of the two-part test. As noted above, this core of the Court’s rationale is a concern for a claim’s overbreadth, specifically the capacity for *preemption*: absent an intervention by the Court, the statutory patent law might not bar patent claims drafted in a manner that might prevent access to the basic tools of science and technology, thereby permitting the patent system to operate contrary to its constitutional purpose to promote progress in the useful arts.

This aspect of the “implicit exception” jurisprudence, however, goes entirely to the *manner in which inventions may be claimed*, and (as noted above) merely assumes the availability of *patent drafting techniques* that might end-run the bar on patenting of abstract concepts by themselves to produce valid patent claims. As such, the rationale stated by the Court has *little to do with subject matter eligibility*—it goes instead to the permitted scope of protection under a valid patent claim and what the enforcement of the patent rights can preclude or preempt.

However, much statutory patent law already exists, specifically under 35 U.S.C. § 112, that addresses limitations on the drafting of valid patent claims. Indeed, the § 112 statutory patent law specifically targets claims that might preempt or prevent access to an underlying concept on which a claimed invention is based or to which it otherwise relates. Most specifically, there is abundant and relevant Supreme Court jurisprudence holding patents seeking to protect an abstract concept are invariably unpatentable because such patents inevitably fail the *statutory requirement* that all valid patent claims must be supported by a *sufficient disclosure* in the patent specification.<sup>26</sup>

To be valid, patent claims—and their discrete elements—must identify what the invention is other than simply through a functional or otherwise conceptual description of how the invention is to function. Similarly, valid patent claims must enable an invention to be both made and used in a manner commensurate with the scope of protection being sought. These statutory “written description” and “enablement” requirements,<sup>27</sup> as interpreted by the courts, are

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<sup>26</sup> *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946) and *O’Reilly v. Morse*, 56 U.S. 62 (1854).

<sup>27</sup> 35 U.S.C. § 112(a). See *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998), in which the patent sought to protect insulin cDNA compounds, broadly with respect to all mammals and specifically with respect to humans. The patent, however, failed to identify the actual structure for human insulin cDNA or the structures for all mammalian insulin cDNA compounds. The patent’s description, because it was effectively limited to no more than the *concept* of the DNA compounds that could code for human and other mammalian insulin proteins (rather than the identification of actual substances themselves capable of doing so), was insufficient under § 112(a). “A written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula, [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *Id.* at 1568 (alteration in original) (citation omitted). See also *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc), in which the Federal Circuit noted that the appealed “claims are . . . genus claims, encompassing the use of all substances that achieve the desired result of reducing the binding of NF- $\kappa$ B to NF- $\kappa$ B recognition sites.” *Id.* at 1341. In invalidating the claims under the § 112(a) “written description” requirement, the Federal

by themselves enough to bar a claim to an invention drafted to broadly as to ensnare any process, machine, manufacture, or composition of matter that might be capable of carrying forth a specified natural law or phenomenon or other abstract concept.

In addition, other statutory requirements for definiteness in claiming (invalidating claims where the scope of protection under the patent is not set out in the claim with reasonable certainty<sup>28</sup>) and for restricting the protection under claim elements set out in merely functional terms (restricting the protection accorded under such claim elements to the patent specification's disclosed structures, materials, or acts and their equivalents for carrying out the stated function<sup>29</sup>) operate in conjunction with the disclosure sufficiency requirements to eliminate any possibility that a valid patent claim could be enforced in a preemptive or preclusive manner with respect to a natural law or phenomenon or other abstract concept.

Looking to the patent statute as a whole, there is no sustainable case to be made for imposing an “implicit exception” that is designed to counter the possible preemption of an abstract concept, much less one with the potential to go far beyond the existing requirement that valid patent claims must be restricted to *specified statutory categories* and supported by a *sufficient disclosure*. It is in this context that the Supreme Court has set out its two-part test.

#### *The Two-Part Test Is Subjective and Arbitrary in Its Application*

In administering this test, the courts have had great difficulty making good sense out of either its “directed to” or “significantly more” prong. Experience in the courts thus far indicates that both prongs of this test can be applied in an arbitrary manner to achieve whatever result on patent eligibility the adjudicator of the issue might desire.

As to the first prong, all claimed inventions—at some level—depend upon associated concepts. All claimed inventions can be distilled and expressed in terms of ever-higher degrees of abstraction until the expression ultimately becomes no more than an abstract idea to which the claimed invention can be said to be directed. On the other hand, as discussed above, any claim meeting the explicit statutory requirements for patent eligibility under § 101 must be directed to “new and useful process, machine, manufacture, or composition of matter or a new and useful improvement thereto”—in essence (as noted above) to a *practically useful*<sup>30</sup> *embodiment or application of any abstract concept to which the claimed invention might relate*.

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Circuit noted that “[s]uch claims merely recite a description of the problem to be solved while claiming all solutions to it and . . . cover any compound later actually invented and determined to fall within the claim’s functional boundaries . . .” *Id.* at 1353.

<sup>28</sup> 35 U.S.C. § 112(b). Under Section 112(b), “a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014).

<sup>29</sup> 35 U.S.C. § 112(f).

<sup>30</sup> *Brenner v. Manson*, 383 U.S. 519 (1966), setting out a § 101 requirement for a *practical* use for an invention to be patentable. See also, *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). “Courts have used the labels ‘practical utility’ and ‘real world’ utility interchangeably in determining whether an invention offers a ‘substantial’ utility.”

Hence, deciding whether a claimed invention meets or fails to meet the first prong of the two-part inquiry can be an entirely discretionary inquiry, at least for any claimed invention that would otherwise be statutorily patentable under the explicit conditions and requirements for patentability. Either result can be justified by a person charged with the adjudication.

The second prong of the two-part can be no less arbitrary in its application. The notion that a claim to an invention must contain “significantly more,” such that the claim evidences an “inventive concept” should be automatically satisfied for any patent claim that is valid under the explicit patentability requirements in the patent statute. Taken as a whole, the subject matter claimed in a valid patent claim must be inventive—non-obvious—or the claimed invention will not pass muster under 35 U.S.C. § 103.

On the other hand, even a statutorily non-obvious patent claim is nonetheless typically composed of some combination of materials or structures previously known—none of which could possibly be “inventive.” Unless the “inventive concept” formulation is necessarily satisfied if the claimed invention was statutorily non-obvious—which would entirely nullify the test—the second prong of the two-part test can amount to a rudderless inquiry. No one can predict with any certainty the direction the analysis will take.

#### *Congress Needs to Act to Abrogate the “Implicit Exception” and Two-Part Test*

The nature and scope of the “implicit exception” problems facing the patent system suggests that vastly more than tinkering with the implicit exception is essential to restore the patent law to a state of equanimity. The flawed premises on which the test was constructed is no less than an unsupportable foundation on which to remodel its existing framework to any acceptable end.

Excision of this jurisprudence from the patent laws, thus, represents not just the optimal, but the only rational, path forward. However, given that such may not be legislatively attainable through a naked abrogation, removal of the test cannot be the sole congressional response—at least in the present environment. Thus, the great challenge in completing any legislative journey lies in identifying such new statutory eligibility limitations that, if coupled with and abrogation, would make it politically possible.

#### *Analysis of Possible New Eligibility Limitations to Supersede the Implicit Exception*

Over the past two years, many approaches have been suggested and developed for ending what critics of the Supreme Court’s jurisprudence regard as the growing nightmare of the “implicit exception.” For the reasons discussed above, the focus of such efforts has increasingly turned to finding a *superseding framework* for defining patent-eligible subject matter. Under such a *superseding framework*, the implicit exception and its two-part framework would become inoperable and then replaced with some additional eligibility requirement to be expressly set out in an amended § 101.

Such an exercise can most productively proceed if a set of shared beliefs can be developed as the legislative justification for Congress to act. Such beliefs should define the

rationale for not leaving the matter to the Courts. They should suggest the direction those superseding statutory requirements on patent eligibility might take—what they should accomplish. Based on the above analysis, the following is offered as a possible summary of how best to frame and guide the task ahead for any discussion with Congress:

1. The Supreme Court’s “implicit exception” is unnecessary to preclude the ability to secure a valid patent a natural law or phenomenon or other abstract concept as such. *The statutory requirements for patentability serve to bar the grant of valid patent claims on such subject matter as such.*
2. The core rationale for imposing the two-part test—to prevent patent drafting techniques from circumventing the bar on patenting abstract concepts—is fully addressed by the statutory patentability requirements mandating a sufficient disclosure and reasonable certainty in claiming, as well as those limiting functionally expressed claim elements to only these structures actually disclosed in the patent specification. *Supreme Court precedents on sufficiency of disclosure—independent of eligibility considerations—make clear that a claim drafted as a tool to preempt an abstract concept can never be validly patented.*
3. Even if there were a colorable justification for imposing the two-part test, it sets out a standard that is unpredictable and essentially arbitrary in its operation. *Were it a statutory test, it would fail to pass constitutional muster. As a judicially imposed standard, it can be no less infirm.*
4. If legislation can be focused on the abrogation of the implicit exception and the two-part test used to implement it, then any superseding limitations on patent eligibility should be crafted through a set of agreed principles. Such principles should serve a filtering function to assure that the inventing community will not find the legislative “cure” to be worse than the judicial “disease.” *Most of all, such principles should reflect the important role of the patent system in affording property rights that can be the basis for investments needed to develop and commercialize new technology that can be of profound public benefit—transparent, objective, predictable, and simple rules must define all aspects of patentability.*

If the above messaging—or some variation of it—were to be accepted as a set of shared beliefs to be used as a starting point for future congressional discussions over patent eligibility legislation, the next step towards a consensus on a legislative path forward should be the development of the set of legislative principles—the filtering criteria—for determining any new legislated limitations on subject matter eligibility for patenting that would be both acceptable on patent policy grounds and suffice as a political matter to see such reforms through to enactment.

These principled filtering criteria could then guide the determination of whether specific proposals imposing such additional statutory limitations on patent eligibility would be deserving of a concerted legislative effort. As an example of the types of principled filtering criteria to be developed, the following are offered:

1. Absent an overarching policy/political objective that would dictate otherwise, patent rights should remain available for discoveries as broadly as the constitutional provision authorizing Congress to enact laws permits. *If any greater restrictions are to be imposed statutorily, they should be entirely driven by political necessity.*
2. Any limitations on subject matter eligibility for patenting should be consistent with the non-discrimination criteria under the TRIPS agreement<sup>31</sup> with respect to the field of technology of the claimed invention. *In addition, they should permit patents in all fields of technology, as mandated under TRIPS, without limitation or restriction.*
3. Similarly, any effort to limit patent eligibility in the United States, beyond the requirements currently explicit in § 101, should be cognizant of international norms for assessing subject matter that is eligible for patenting. *One objective should be to secure at least parity with standards permitting patents to be granted in other industrialized, technology-creating countries.*
4. To the preceding end, any patent-eligibility limitations should not be inconsistent with efforts to further greater international harmonization of approaches to patent-eligibility determinations among industrialized countries. *In this respect, Congress should avoid re-creating entirely unique eligibility concepts (e.g., such as the existing two-part test). In this way, precedents on patent eligibility outside the United States could offer guidance to such determinations in the United States.*
5. Overall, any new statutory patent-eligibility limitations be amendable to objective, predictable, and administrable standards for determining eligible subject matter that make clear what otherwise patentable subject matter would be rendered unpatentable. *It would be untenable to replace a standard now seen by many as arbitrary in its application with one that might prove similarly opaque or obscure in identifying what otherwise patentable subject matter would be rendered patent ineligible.*
6. Any new limitation on patent eligibility should consider the proposed limitation's consonance with the constitutional purpose of the patent system to promote progress in the useful arts. *In this respect, nothing in the Constitution authorizes Congress to enact patent laws to provide exclusive rights on subject matter that contributes only to arts other than the useful arts.*
7. An optimal superseding limitation on patent eligibility should put an end to the need for piecemeal legislative efforts to curtail patent eligibility. *Examples of such are the limitation on remedies for non-technological medical and surgical procedures,<sup>32</sup> the*

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<sup>31</sup> See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), hereinafter the TRIPS Agreement, Article 27.1: “[P]atents shall be available for any inventions, whether products or processes, *in all fields of technology*, . . . patents shall be available and patent rights enjoyable *without discrimination as to . . . the field of technology*,” (Emphasis added).

<sup>32</sup> 35 U.S.C. § 287(c).

*prior art provision applicable to non-technological tax strategy patents,<sup>33</sup> the bar on patenting of human organisms,<sup>34</sup> and the transitional procedures for covered business method patents.<sup>35</sup>*

## **Contours for a Superseding Limitation on Patent Eligibility—Politically Viable Avenues**

### **Present Efforts Within the Patent Community to Examine § 101 Legislation**

Much important work is now underway within the patent community to address the problems present in Supreme Court patent-eligibility jurisprudence. More than a year ago, the American Intellectual Property Association previewed at its annual meeting a number of possible legislative avenues for redressing the Supreme Court's § 101 jurisprudence, featuring presentations from members of its task force on patent eligibility.<sup>36</sup>

The Intellectual Property Law Section of the American Bar Association is examining legislative approaches to amending § 101 through its own task force effort, with the hope that common ground might emerge through these efforts.<sup>37</sup> In addition, the Intellectual Property Owners Association similarly has a subject-matter eligibility task force effort underway.<sup>38</sup>

The Center for the Protection of Intellectual Property convened a Section 101 Working Group at the end of 2015 to address patent-eligibility issues and their possible legislative resolution.<sup>39</sup> Finally, the Naples Roundtable extensively considered the issue of patent eligibility at its 2016 meeting.<sup>40</sup> It plans yet another examination of this issue at its 2017 meeting.<sup>41</sup>

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<sup>33</sup> Leahy-Smith America Invents Act, Public Law 112-29 (September 16, 2011), § 14.

<sup>34</sup> *Id.*, § 33.

<sup>35</sup> *Id.*, § 18.

<sup>36</sup> President's Forum at AIPLA Annual Meeting to Address Patent Eligible Subject Matter, October 24, 2015, <http://www.aipla.org/about/newsroom/PR/Pages/151021PressRelease.aspx>. The forum addressed: *Patent Eligible Subject Matter: The Search for Solutions to a Growing Problem*.

<sup>37</sup> “The Council also heard a presentation on Section 101 subject matter eligibility issues, from Jonathan Sick, Chair of the Patents Division. Mr. Sick provided a brief update on the progress of the task force working on the issues involved. He noted that the task force was focuses on developing proposals for legislative policy that all the major IP organizations could get behind. Although no action was being requested at the August meeting, it was possible that a consensus might be asked of Council at the November Council Meeting.” ABA-IPL eNews September 2016 (available at [http://www.americanbar.org/publications/section\\_enews\\_home/aba-ipl-enews-2016-09.html](http://www.americanbar.org/publications/section_enews_home/aba-ipl-enews-2016-09.html)).

<sup>38</sup> IPO Section 101 Legislation Task force at <https://www.ipo.org/index.php/about-ipo/committees/section-101-legislation-task-force/>.

<sup>39</sup> Reported at <http://cpip.gmu.edu/activities/events/>.

<sup>40</sup> The roundtable's agenda included as topics: “To what extent is the Patent System served by judicially extending denial of patent eligibility under 35 U.S.C. § 101 beyond the concept of obviousness as enacted in 35 U.S.C. § 103? What subject matter lacks patent-eligibility that is *not* already denied patentability under §§ 102, 103, 112? How broadly should the § 101 eligibility standard be applied; e.g., in the biotech area, for medical diagnostics, and for all machines controlled by any computer program?” (See <https://www.thenaplesroundtable.org/issues-and-papers/papers-2/>).

<sup>41</sup> See [https://www.thenaplesroundtable.org/wp-content/uploads/2016/10/2017-Patent-Experts-Conference-Social-Events-Participating-Judges-and-Agenda-10.7.16.rev\\_2.docx](https://www.thenaplesroundtable.org/wp-content/uploads/2016/10/2017-Patent-Experts-Conference-Social-Events-Participating-Judges-and-Agenda-10.7.16.rev_2.docx).

From the above exercises and others, it appears that Congress may have the opportunity to consider no small quantity of work product in the quest for a viable avenue for addressing the Supreme Court's § 101 jurisprudence. Indeed, there may be as many views on the exact form § 101 should take, if amended by Congress, as there are constituencies within the patent system. However, the essential aim for all of these efforts must not be to simply expose all avenues for moving forward with legislation, but to ultimately converge on a single approach that yields a single legislative text.

Coming to a single approach is complicated by many factors. As noted above, one issue is political. *What might be legislatively viable?* Many issues are substantive. *What is the principled bright line a new law on patent eligibility should draw?* Perhaps the most unpredictable factor, however, once a legislative campaign begins, is the level of interest of the general public it will engender—and the questions that, if raised, will need cogent answers. *Are patents to be allowed for subject matter such as human genes and human organisms?*

### **Background Concerns – The Public Interest in § 101 Eligibility Issues**

Historically, any effort to modify the provisions of § 101 enacted under the 1952 Patent Act in any manner has met with opposition from those concerned that opening § 101 is the opening of the Pandora's Box among the statutory sections of the patent law. Almost unique to § 101, there is a public interest (and an interest by the broader public) in patent-eligibility law that extends well beyond any patent constituencies.

The justified concern among legislators is that it might be fruitless to open this section of the patent statute to amendment unless there were some reasonable prospect of a broad consensus on what the targeted, needed amendment might be. Particularly needed is a clear articulation of what the amended law might do—and how and why.

Legislatively opening the issue of subject matter eligibility is likely to initiate a wide-ranging, potentially even media-frenzied, discussion of the areas where the patent system should and should not reach. This means opening a dialogue that holds an inevitable potential to run far afield of simple legal concerns.

There are those who will argue that philosophical, economic, moral, and ethical considerations should be part of any discussion of § 101's permitted scope of eligible protection. Thus, among other issues, it may be difficult to keep the central focus of congressional deliberations on the constitutional aim of the patent laws, *i.e.*, that they exist to promote the disclosure of new technology and thereby promote progress in the useful arts.

Arenas where non-technology concerns over patenting are likely to come into play range from the patenting of human genes to the availability of patents for software implemented inventions. This makes it important to start the quest for any new, superseding limitations with legal eyes wide open to the non-legal concerns that must be addressed and must be taken account of as any legislative process advances. *It makes it vital for any legislative proposal that surfaces to explain exactly how the proposal will impact areas of patenting of an intense interest by non-patent constituencies.*

## Two Approaches – “Reprising” Requirements vs. a “Field of Technology” Limit

In the face of the colossus of ongoing § 101 re-drafting efforts within the patent community, this submission will not attempt to inventory, much less analyze, all possible legislative approaches to amending § 101. Instead, it will contrast what appear to be the two most viable approaches for superseding the current Supreme Court jurisprudence—and look to the legal aspects of each.

The most superficially attractive approach can be best characterized as an effort to *reprise* existing statutory patentability requirements as new ones, specifically as eligibility limitations. The aim of these reprising efforts is to introduce a new eligibility requirement into § 101 that operates by merely barring the patenting of subject matter that is already unpatentable under the existing provisions of the patent statute.

A second viable approach—and one that was specifically designed to implement the filtering principles above—is based on codifying a “field of technology” limitation on patent eligibility. As discussed below, this approach would impose a new and substantive statutory limitation on the availability of patents that is nowhere to be found in the existing patent statute.

In the latter regard, Appendix A is offered as a prototype legislative proposal that would implement a “field of technology” limitation on patent eligibility.

### “Reprising” Existing Statutory Requirements for Patentability as Eligibility Limits

#### *“Practically Useful Embodiment or Application” Limitation on Eligibility*

As set out in the Lilly, *et al.* amicus brief, “the patent statute explicitly limits patenting to physical embodiments, *things* and *act-based processes*” and this limitation means that such embodiment-based claims “can only ever be *applications* of any related concept and can never be the concept itself.”<sup>42</sup> Moreover, as noted above, the patent statute itself mandates only *practically useful* inventions can be patented.<sup>43</sup>

The most cogent interpretation of the statutory requirements currently set out in § 101 is that they bar patents on any subject matter that is not a *practically useful embodiment or application* of any natural law or phenomenon or other abstract concept associated with a claimed invention or otherwise related to it. Indeed, it is difficult to imagine just how these existing statutory requirements might be interpreted to any other effect or meaning.

The foregoing observations on the existing statutory requirements is the jumping-off point for proposals to amend § 101 to moot the implicit exception and replace the judge-made exception with a new statutory requirement that a claimed invention must be a practically useful

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<sup>42</sup> Appendix B at B5 (Emphasis in original).

<sup>43</sup> “The contemporary statutory requirements under § 101, § 103 and § 112(a) together operate to limit valid patent claims to *inventive* and *practically useful applications* of any law, phenomenon, or idea to which a claimed invention relates.” *Ibid.*

(or at least a “practical”) embodiment or application of any natural law or phenomenon or other abstract concept on which the claimed invention is based or to which it otherwise relates.<sup>44</sup>

### *“Human Activity” and “Human Mind” Limitations on Eligibility*

Patent claims confined to subject matter that exists in nature independently of, and prior to, any human activity, or that exists solely in the human mind, are the hallmark of statutorily unpatentable subject matter under the explicit § 101 requirements. Without human activity, there is no inventor and can be no invention.

The courts have long recognized that some human activity is needed for patentability because what otherwise is already present in the physical world (whether or not known to be present) cannot be regarded as being statutorily “new” under § 101 (or novel under 35 U.S.C. § 102) by virtue of the ancient Supreme Court doctrine of *inherent anticipation*.<sup>45</sup> Similarly, subject matter existing solely in the human mind<sup>46</sup> can have no practical *usefulness* under § 101, much less represent an *embodiment or application* as the statute circumscribes under its *process, machine, manufacture, or composition of matter* limitation on eligibility.

The foregoing observations may have inspired proposals to duplicate these existing statutory patentability requirements with a new eligibility limitation in § 101 under which patent eligibility would be barred for patent claims directed to subject matter that exists in nature independently of, and prior to, any human activity, or that exists solely in the human mind. Such a human activity/human mind limitation, like the *practically useful embodiment or application* approach, would be coupled with a further provision mooted the implicit exception.

### *Benefits and Difficulties with a “Reprising” Approach to § 101 Legislation*

The *practically useful embodiment and application* and *human mind/human activity* approaches meet several of the filtering principles outlined above. As a result, they should not be dismissed out of hand.

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<sup>44</sup> These proposals have been constructed under one of two possible frameworks. One such framework for enacting this practically useful embodiment or application requirement would be as part of an amendment that concurrently overruled the implicit exception and the use of the two-part test implementing it. The alternative framework would leave the implicit exception nominally in place, but dictate that two-part test would automatically be met whenever the new practically useful embodiment or application limitation was satisfied. Under either framework, once the new statutory limitation had been met (*i.e.*, the claimed invention is found to be a practically useful embodiment or application of any associated concept), any further application of the implicit exception and its two-part test is abrogated. Thus, any difference as between these two possible implementing frameworks is entirely cosmetic.

<sup>45</sup> As noted earlier, the statutory for being “new” under § 101 or novel under 35 U.S.C. § 102 bars the patenting of any subject matter that exists or operates in nature under *Peters v. Active Mfg. Co.*, *supra*.

<sup>46</sup> The language used to express the “human mind” limitation is not entirely self-explanatory. It appears that the proponents of this approach are seeking to bar claims to entirely mental processes, that is, processes composed of entirely mental steps. This same language, however, might be intended to cover only processes expressed so broadly as to be capable of being performed either through some physical act or through mental thoughts. In general, steps written in such a conceptual manner that they can be performed mentally as well as physically raise the sufficiency of disclosure issues that operate either to bar patentability under § 112(a) or § 112(b) or limit the claim to disclosed embodiments under § 112(f). However interpreted, the “human mind” limitation does not appear to render any otherwise patentable subject matter unpatentable on eligibility grounds.

Importantly, they hold the promise of wide acceptance within many inventor and patent-owning communities. In effect, they can be conceptualized as the addition of *transparent clothing* to a *naked abrogation* of the implicit exception and the two-part test. Once this transparent clothing is seen through, however, these new limitations appear to add nothing of substance to the existing statutory conditions and requirements for patentability. Subject matter that, but for the new limitations would be statutory patentable, would remain patent-eligible and patentable applying the new limitations.<sup>47</sup>

The above virtue, however, may be a disguised Achilles' heel were such proposals to be advanced in Congress. As currently crafted, these approaches can be expected to raise the same type of political viability questions that are seen by many as the political death knell of a naked abrogation of the implicit exception and its two-part implementing test. If a naked abrogation of the implicit exception would be problematic to accomplish *de jure*, to do so *de facto* is unlikely to be any easier to achieve.

The proponents of these “reprising” approaches are likely to continue to develop and refine them. Future iterations may be offered that do more than simply *de facto* overrule the implicit exception and the two-part test—by offering new limitations on patentability beyond what is presently required under the patent statute. Such efforts might well render one or more of these approaches as potentially viable as they are potentially attractive.

### **A Constitutionally Consonant “Field of Technology” Eligibility Limitation**

As efforts at addressing the implicit exception legislatively move beyond the *de jure* or a *de facto* abrogation approaches discussed above, the exercise becomes more sobering for at least some inventors. An inevitable consequence of a true superseding approach (*i.e.*, the imposition of a substantively new requirement for patent eligibility as the implicit exception is overruled) is that some claimed inventions that would have been routinely found patent-eligible by the USPTO—particularly during the dozen year period between the *State Street Bank*<sup>48</sup> and *Bilski*<sup>49</sup> decisions—will not meet any heightened statutory eligibility requirement that supersedes the non-statutory implicit exception.

This realization, however, need not be a fatal obstacle to finding a consensus on remedial legislation. Indeed, the more faithfully a new statutory limitation adheres to the filtering

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<sup>47</sup> The proponents of these reprising approaches correctly point out that their new patent-eligibility requirements do not foreclose the possibility that they could be interpreted by the courts to find otherwise statutorily patentable subject matter to be patent-ineligible. Thus, these approaches could amount to more than a naked abrogation of the implicit exception under an *uncertainty principle*—like all new statutory requirements, their exact parameters won't be known until the courts get around to interpreting them. The proponents, however, have not otherwise indicated what type of objective, predictable, and administrable standard might apply if these approaches were to be interpreted to go beyond existing patentability requirement in limiting patentability.

<sup>48</sup> *State Street Bank & Trust Co. v. Signature Financial Group*, 149 F. 3d 1368, 1375 (Fed. Cir. 1998), “For [the] purpose of our analysis ... claim 1 is directed to a machine programmed with ... software and admittedly produces a ‘useful, concrete, and tangible result.’ ... This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.”

<sup>49</sup> *Id.*

principles set out above, the lesser the prospect that the new standards that will be seen by any substantial community of inventors as a legislative cure worse than the judicial disease.

Moreover, adherence to these principles suggests constructing a legislative approach that would make only a single and relative simple addition to § 101. One purpose of the present submission is to suggest that introducing a straightforward “field of technology” limitation on eligibility into the patent statute may be—in the present environment—the single and simple addition to § 101 that constitutes the legislative path forward most worthy of further examination. As noted above, a prototype of such a proposal is set out in Appendix A.

Any reading of Article I, Section 8, Clause 8 of the Constitution indicates that patent-eligible subject matter must be the work of an *inventor*—and that subject matter must amount to a *discovery*. The existing eligibility provisions of § 101 already fully account for these aspects of the constitutional authorization for Congress to enact patent laws.

Additionally, the laws authorizing an invention’s patenting must be constitutionally calculated *to promote progress in the useful arts*. This constitutional architecture suggests two limitations on the ability to patent—not current set out with the same degree of specificity in the patent statute—that Congress might utilize as the predicate for enacting further statutory hurdles on subject matter qualifying as eligible for patenting.

The first such potential limitation relates to the “useful arts” themselves. A discovery of no possible benefit to the useful arts could be viewed as failing to qualify constitutionally for patenting. The second potential limitation arises from the “promoting progress” portion of this constitutional clause. This limitation might be read to imply that an inventor’s patent-eligible discovery must make some *contribution to the useful arts*.

If these limitations are to be accepted as constitutional constraints on congressional authority to enact patent laws, then *subject matter failing to make a contribution to the useful arts* could be regarded constitutionally ineligible for patenting. If so, then an amendment to § 101 might be drafted to make this constitutional constraint more explicit in § 101.

If the above is accepted, then it is constitutionally self-evident that not all *arts* would qualify as *useful arts*.<sup>50</sup> A new § 101 eligibility hurdle to codify this self-evident limitation on the nature of patent-eligible inventions through a provision setting out with particularity the patent-eligible arts to which a claimed invention must contribute.

The *useful arts* have traditionally—and today—been understood arts arising within a *trade*, specifically a *vocation in a technological field of endeavor*. The term “useful arts,”

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<sup>50</sup> “[W]ith regard to patentability specifically, the importance of the [constitutional] word ‘useful’ is to enable patentability for processes and methods, as systems of rules, but only with respect to their contribution to a patentable ‘trade.’ A ‘new and useful art’ should then be read to mean either (a) an invented system of new rules applying to an existing trade, or (b) a system of rules specifying a new trade. . . . [A] “trade” [can be defined] as being ‘distinguished from the liberal arts and learned professions, and from agriculture.’” Brief of Amicus Tony Dutra in Support of Respondents (Feb. 27, 2014), *Alice Corp. v. CLS Bank* (App. No. 13-298) at p. 8, available at [http://www.americanbar.org/content/dam/aba/publications/supreme\\_court\\_preview/briefs-v3/13-298\\_resp\\_amcu\\_td.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/publications/supreme_court_preview/briefs-v3/13-298_resp_amcu_td.authcheckdam.pdf).

however, has never been a static concept. Nothing about the *useful arts* concept was set in stone in the summer of 1787 as the Constitution was being drafted. Indeed, new *trades* continue to arise, just as improvements continue to be made *existing trades*, based upon *discoveries* made by *inventors*.

Traditionally, however, the *useful arts* have always been distinguished from the *fine arts*. The artisans contributing to the “useful arts” have also been distinguished from practitioners comprising the learned professions—and from farmers, or businessmen. The best linguistic representation of this touchstone might be contemporarily expressed as a dichotomy between *technologically* and *non-technologically* based pursuits.

Such distinguishing dichotomies as set forth above hold the potential of being developed into a more objective and predictable test for subject matter eligibility for patenting than the two-part test. The new test, expressed as a statutory standard, could demand no more than that a claimed invention must contribute to the *useful arts*, defined as a *field of technology*.

Under such a new statutory eligibility requirement, except for a discovery that claimed in terms of some technological innovation, the mere movements of physician’s or surgeon’s hands treating a patient would become patent ineligible. Similarly, a lawyer’s new estate planning scheme or an accountant’s new tax preparation system would fail this eligibility standard, absent contributing to a technological field.

Processes, methods or practices otherwise in such learned fields of endeavor, even though making profoundly important contributions to the *art* of such professions, would be cut off from the patent system on subject matter grounds. This would be so even if such subject matter were nominally expressed in the form of a process or machine.

The same would apply to businessmen engaging in non-technological business practices. Even if such individuals were deemed to be “inventors” and their handiwork deemed a “discovery,” such work would fail the test of contributing to the useful arts in a manner promoting their progress.<sup>51</sup>

Were the U.S. patent system to be constitutionally constrained in this manner it would move in a direction consistent with the manner in which patent eligibility is assessed in other industrialized countries.

It would be fully consistent with the obligations of the United States under international treaties, most especially TRIPS.

It would address the concerns of constituencies who in recent decades have caused Congress to amend the patent laws to address remedies for infringement of medical and surgical procedures, prior art for tax preparation patents, patent protection for human organisms, and special procedures for non-technological business method patents.

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<sup>51</sup> See, generally, *Kappos v. Bilski* at 130 S. Ct. 3243-3244 (J. Stevens, concurring).

In the latter regard, it would eliminate from patent eligibility the subject matter of all these special provisions eviscerating patent rights that were made part of the patent law in recent years.

### *Conclusions*

Any legislative proposal addressing § 101 patent-eligibility issues should begin—and ideally end—with the abrogation of the “implicit exception” and the two-part test used to implement it. A close examination of the statutory patent law would indicate that there is neither a constitutional nor a policy reason for the Congress to do other than overrule this judge-made foray into patent eligibility.

If some superseding statutory patent-eligibility test to accompany the abrogation of the implicit exception and its two-part test, a number of filtering principles should apply to rule out approaches that would be no better than the existing judicial morass. This would include ruling out any new statutory standard that did not draw a clear line identifying what otherwise patentable subject matter a new § 101 eligibility hurdle would render unpatentable—specifically, what objective, predictable, and administrable test would apply to render unpatentable the otherwise statutorily patentable.

If political viability proves to be a fatal impediment to beginning and ending § 101 reforms with no more than a naked abrogation of the implicit exception, careful consideration should be given to refining a new “field of technology” limitation on subject matter eligible for patenting. The contours of such an approach have the potential to address—and redress—what many complainants over the reach of the patent laws see as an unjustified intrusion of patent rights into non-technological arenas in which granting patents has no possible justification.

Right or wrong, these complainants have managed to convince Congress to amend the patent statute to limit patent rights in ways that would have been unneeded had the patent statute itself explained that patents exist solely are to protect technology, *i.e.*, discoveries that can contribute to—and thereby promote progress in—the useful arts. Such an express eligibility limitation added to § 101—*one stating no more than an inventor shall be entitled to a patent for an invention that contributes to the useful arts, which arts are defined as all fields of technology without restriction or limitation*—might be all the new statutory law needed to supersede all the old judge-made law.

**APPENDIX A**  
*DISCUSSION DRAFT*  
**A PROTOTYPE LEGISLATIVE PROPOSAL INTRODUCING**  
**A “FIELD OF TECHNOLOGY” RESTRICTION ON PATENT ELIGIBILITY**

***Introduction***

The following is offered as a prototype for legislation that might be enacted by Congress to introduce needed reforms to the law on subject matter eligibility for patenting. The prototype overrules the so-called “implicit exception” created under Supreme Court jurisprudence, including the Court’s two-part test it established to implement it.

The “implicit exception” bars patents on a natural law or phenomenon or other abstract concept and the implementing two-part test more specifically bars patenting a claimed invention (1) directed to such an abstract concept that (2) does not set out significantly more in the claim, specifically some inventive concept.

The prototype legislation replaces this jurisprudence with explicit subject matter limitations on patent eligibility. These new limitations are added to a new 35 U.S.C. § 101 that supersedes § 101 as enacted under the 1952 Patent Act.

In addition, ancillary amendments are made to the patent laws in order to assemble a unitary package of changes to the law on subject matter eligibility. In the aggregate, the proposed legislative changes account for a wide-ranging set of constitutional, ethical, philosophical, practical, and policy concerns over the reach of the patent laws.

***Prototype Legislative Text***

(a) CODIFIED PATENT ELIGIBILITY STANDARD.—

(1) Strike section 101 of title 35, United States Code, and insert:

**“§ 101. Right to patent inventions; eligible subject matter required**

“(a) RIGHT TO A PATENT; USEFUL ARTS DEFINED.—An inventor shall be entitled to a patent for an invention that contributes to the useful arts, absent a finding that one or more conditions or requirements under this title have not been met. For the purposes of this section, the useful arts refer to all fields of technology, without restriction or limitation.

“(b) ELIGIBLE CATEGORIES; PRACTICAL UTILITY REQUIRED.—Subject matter may not be patented unless claimed in terms of a practically useful process, machine, manufacture, or composition of matter, or a practically useful improvement thereto.

“(c) ELIGIBLE SUBJECT MATTER LIMITATION; RELATIONSHIP TO ABSTRACT CONCEPTS.—For the purposes of this section, the discovery of a natural law or phenomenon or other abstract concept shall be deemed not to contribute to the useful arts. Notwithstanding the preceding sentence, eligibility for patenting under this section shall not be negated because a claimed invention is based upon or otherwise relates to an abstract concept.

“(d) ADDITIONAL LIMITATIONS AND EXCEPTIONS BARRED.—No additional limitations on or exceptions to eligibility for patenting shall exist or may be implied for a claimed invention that meets the requirements for eligibility under this section.

(2) The section heading for section 101 of title 35, United States Code, is amended to read as follows:

“§ 101. Right to patent inventions; eligible subject matter”

(3) In section 102 of title 35, United States Code, strike “A person shall be entitled to a patent unless” and insert “A patent for a claimed invention may not be obtained if”

(4) Section 287(c) of title 35, United States Code, and Sections 14 and 33 of the Leahy-Smith America Invents Act, Public Law 112-29 (September 16, 2011), are repealed.

(5) In Section 18 of the Leahy-Smith America Invents Act, for any claimed invention for which the amendments made under this subsection to section 101 of title 35, United States Code, apply—

(A) the term “technological invention” shall mean a claimed invention that is eligible for patenting under amended section 101;

(B) the regulations promulgated pursuant to paragraph (d)(2) shall be inapplicable; and

(C) the rule of construction under subsection (e) shall be inapplicable.

(b) EFFECTIVE DATE AND EFFECT.—

(1) IN GENERAL.—The amendments under subsection (a) shall take effect six months after the date of enactment of this Act and shall apply to any patent issued before, on, or after the date of enactment, except that such amendments shall not apply to any invalidity defense raised in a civil action brought before six months after the date of enactment.

(2) SAVINGS CLAUSE.—If a claimed invention in a patent issued prior to six months after the date of enactment would not have been invalid had the amendments made by subsection (a) not been enacted, then the validity of the claimed invention shall be determined as though such amendments had not been enacted into law.

(3) ELECTION BY APPLICANT IN PRE-ENACTMENT PATENT FILINGS.—Notwithstanding paragraphs (1) and (2), in an application filed before the date of enactment of this Act and pending before the Patent and Trademark Office six months after the date of enactment, the applicant may within nine months of the date of enactment elect to have the patentability and enforceability of the claims in the application and any patent issued thereon determined as though the amendments under subsection (a) had not been enacted into law. Any such election shall be in writing, shall specify the patents and applications for patent to which the election relates, and shall otherwise meet any requirements that the Director may impose by regulation.

## Summary of the Prototype Legislative Proposal

### Overview

The Supreme Court has determined that no explicit requirement in the patent statute necessarily and unambiguously bars the patenting of natural laws and phenomena and other abstract concepts. As a consequence of its finding that there is no such explicit bar, the Court has held that this type of abstract subject matter should be found ineligible for patenting under § 101 of Title 35, as enacted under the 1952 Patent Act. The Court has held that § 101 includes an “implicit exception” to patent eligibility barring the patenting of such subject matter.<sup>1</sup>

The Court has implemented this implicit exception through what is referred to a two part test. The two-part test denies patent eligibility to a claimed invention (1) found to be *directed to an abstract concept* if such a claim (2) fails to include *significantly more* than the abstract concept itself, *i.e.*, the claimed invention fails to include some *inventive concept*.<sup>2</sup>

The amendment repeals § 101 and replaces it with completely new statutory text. The new § 101 text imposes two new statutory limitations on patent eligibility not explicitly set out in the 1952 Patent Act. These new statutory eligibility limitations obviate the need for the courts to impose any non-statutory exception, including any implicit exception, relating to patent eligibility. This includes the Court’s implicit exception as it relates to abstract concepts and the jurisprudence that implements it, *i.e.*, the two-part test.

To achieve these ends, the amendment both overrules the implicit exception and expressly bars the imposition of any non-statutory requirements for patent eligibility. Thus, under new § 101, neither the implicit exception nor the two-part test implementing it survives as part of the patent laws.

The two new statutory limitations include (1) an explicit bar on the patenting of a natural law or phenomenon or other abstract concept by itself and (2) a requirement that patent-eligible

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<sup>1</sup> The “implicit exception,” discussed further below, purports to bar the ability to patent a natural law or phenomenon or other abstract concept. “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.*, 133 S.Ct. 2107, 2116 (2013) (internal quotation marks and brackets omitted). We have interpreted § 101 and its predecessors in light of this exception for more than 150 years.” Quotation from *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S. Ct. 2347, 2354 (2014).

<sup>2</sup> The reference to the “two-part test,” again discussed further below is also commonly referenced as the *Mayo/Alice* test because its parameters were derived from recent Supreme Court decisions barring patents on subject matter eligibility grounds. “In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012), we 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.’” Quotation from *Alice v. CLS Bank*, at 134 S. Ct. 2355.

inventions must contribute to the useful arts. New § 101 further defines the useful arts as a field of technology.

By obviating the need for the Court’s non-statutory, implicit exception—and overruling the judicial two-part test implementing it—the new statutory limitations on patent eligibility moot the criticisms that the two-part test is arbitrary in its application. Superseding the two-part test with the new statutory limitations outlined above also obviates criticisms that the Court’s implicit-exception jurisprudence produces patent eligibility determinations that are inconsistent with accepted international norms for defining patent-eligible subject matter.

Lastly, new § 101 addresses assertions that the operation of the two-part test may conflict with treaty obligations of the United States to make patents available in all fields of technology in a non-discriminatory manner. The patent-eligibility provisions under new § 101 are necessarily TRIPS-compliant because patents are available in all fields of technology, without restriction or limitation.

### **§ 101(a) – Right to a Patent; Useful Arts Defined**

New § 101(a) provides a “right to patent” provision under which inventors are accorded a right to patent their respective inventions and discoveries, subject to compliance with the various conditions and requirements for patentability set out in the statute. For a patent on a claimed invention to be denied patentability (or be found invalid), new § 101(a) requires that there must be a *finding* that at least one of the statutory conditions or requirements for patentability has not been met.

The affirmative demonstration of invalidity/unpatentability that is required under subsection (a) to negate the right to patent can come through an adjudication by any competent authority. Such a finding could be made, *inter alia*, by the United States Patent and Trademark Office following examination of a claimed invention in a pending patent application under 35 U.S.C. § 131–§ 135, in a judicial action to enforce an issued patent in which an invalidity defense has been raised under 35 U.S.C. § 282(b), in a written decision the Patent Trial and Appeal Board in an inter partes or post grant review under 35 U.S.C. § 318(a) or 35 U.S.C. § 328(a), or in a patent validity adjudication by the International Trade Commission under 19 U.S.C. § 1337.

In addition to this right-to-patent provision, new § 101(a) also contains an explicit limitation on the subject matter that is eligible for patenting. This new limitation on patent eligibility makes ineligible for patenting any claimed invention that fails to contribute to the useful arts.

The new requirement that patent-eligible inventions must contribute to the useful arts is derived from the constitutional limitation on the ability of Congress to afford inventors exclusive rights to their inventions. Under the Constitution’s Article I, Section 8, Clause 8, Congress may act “To promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their respective ... Discoveries.”

Under § 101(a), a definition of those arts qualifying as “useful arts” is provided. This definition states that the useful arts extend to—and are limited to—all fields of technology, without restriction or limitation. This definition serves two separate functions.

First, the “useful arts” definition represents a codification consistent with the dual requirements on patent availability and non-discrimination under the TRIPS treaty.<sup>3</sup> Second, it eliminates from eligibility for patenting any invention or discovery that does not contribute to any technological field.

Under new § 101(a), subject matter contributing to one or more of the arts, but not to the *useful* arts, would be ineligible for patenting. More specifically, subject matter that contributes to one or more fields of human endeavor, but not to any *field of technology*, cannot be patented. As a result, this requirement would bar, as ineligible for patenting, methods for doing business, for estate planning, for tax preparation, for the practice medicine or surgery, or for like fields of human endeavor to the extent they make no contribution to a field of technology.<sup>4</sup>

As a result, the technological field limitation supersedes, though a more general and comprehensive patent-eligibility restriction, the various piecemeal restrictions on patenting and patent rights that have been enacted by Congress in recent decades. These include the provisions in 35 U.S.C. § 287(c) barring certain remedies for a medical or surgical practitioner’s performance of certain non-technological medical or surgical procedures (*e.g.*, activities not involving the use of a patented machine, manufacture, or composition of matter or the patented use of a composition of matter) and §§ 14 and 33 of the Leahy-Smith America Invents Act providing, respectively, that certain non-technological strategies for reducing, avoiding, or deferring tax liability were to be deemed insufficient to differentiate a claimed invention from the prior art, and that no patent may issue on a claim directed to or encompassing a human organism.

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<sup>3</sup> See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), hereinafter the TRIPS Agreement, Article 27.1: “[P]atents shall be available for any inventions, whether products or processes, *in all fields of technology*, . . . patents shall be available and patent rights enjoyable *without discrimination as to . . . the field of technology*,” (Emphasis added).

<sup>4</sup> In effect, this limitation bars patenting in fields of endeavor that have historically been characterized as professional or entrepreneurial rather than a *technological*. “Numerous scholars have suggested that the term ‘useful arts’ was widely understood to encompass the fields that we would now describe as relating to technology or ‘technological arts.’ . . . Thus, fields such as business and finance were not generally considered part of the ‘useful arts’ in the founding Era. See, e.g., The Federalist No. 8, p. 69 (C. Rossiter ed. 1961) (A. Hamilton) (distinguishing between ‘the arts of industry, and the science of finance’); 30 The Writings of George Washington 1745-1799, p. 186 (J. Fitzpatrick ed. 1939) (writing in a letter that ‘our commerce has been considerably curtailed,’ but ‘the useful arts have been almost imperceptible pushed to a considerable degree of perfection’). Indeed, the same delegate to the Constitutional Convention who gave an address in which he listed triumphs in the useful arts distinguished between those arts and the conduct of business. He explained that investors were now attracted to the ‘manufactures and the useful arts,’ much as they had long invested in ‘commerce, navigation, stocks, banks, and insurance companies.’ T. Coxe, A Statement of the Arts and Manufactures of the United States of America for the Year 1810, (1814), in 2 American State Papers, Finance 666, 688 (1832).” *Bilski v. Kappos*, 130 S. Ct. 3218, 3244-3245 (2010), J. Stevens, concurring.

Finally, the courts have heretofore indicated that patent eligibility under § 101 can be a threshold determination in the process of assessing patentability.<sup>5</sup> The new explicit limitation on patent eligibility under § 101(a) sets out a requirement that likewise can be readily determined as a threshold matter, *e.g.*, through a summary adjudication.

### **§ 101(b) – Eligible Categories; Practical Utility Required**

New § 101(b) carries forward two specific requirements from § 101 of the 1952 Patent Act. First, it maintains the traditional subject matter categories that limit the manner in which patentable inventions must be defined, *i.e.*, as “any process, machine, manufacture, or composition of matter or any improvement thereto” Second, the so-called “utility” requirement for patentability under § 101 of the 1952 Patent Act is restated without any substantive change in new § 101(b).

Specifically as to utility, § 101(b) sets out an explicit requirement that patentable inventions must be “practically useful.” The explicit reference to the practicality of the usefulness of an invention required for patentability concisely codifies the holding of the Supreme Court in *Brenner v. Manson*, 383 U.S. 519, 534 (1966).<sup>6</sup>

### **§ 101(c) – Eligible Subject Matter Limitation; Relationship to Abstract Concepts**

New § 101(c) defines a limitation on patent eligible subject matter, as well as confines that limitation. Under § 101(c), a natural law or phenomenon or other abstract concept, as such, cannot be patented. Such categories of subject matter are deemed not to contribute to the useful arts, as required for patent eligibility under new § 101(a).

However, this § 101(c) limitation on patent eligibility is circumscribed by a second provision in § 101(c) that specifically bars negating patent eligibility on the ground that an invention or discovery bears some type of relationship to such an abstract concept.

This provision is a recognition that essentially all inventions have some associated or related natural law or phenomenon or other abstract concept and such an association or relationship by itself should be non-prejudicial to patent eligibility of an otherwise patent eligible invention under amended § 101.

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<sup>5</sup> “Section 101 imposes a threshold condition. ‘[N]o patent is available for a discovery, however useful, novel, and nonobvious, unless it falls within one of the express categories of patentable subject matter.’” Quotation from *Bilski v. Kappos*, at 130 S. Ct. 3236 (2010).

<sup>6</sup> In *Brenner*, the Court addressed “whether the *practical utility* of the compound produced by a chemical process is an essential element in establishing a prima facie case for the patentability of the [claimed] process” by holding that “[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with *substantial utility*,” *i.e.*, patentable inventions are “useful” when “*specific benefit exists in currently available form*.” (Emphasis added.) The Federal Circuit has consistently applied the Court’s holding, further clarifying that a practical utility that must be evidenced for an invention to be patentable. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). “Courts have used the labels ‘practical utility’ and ‘real world’ utility interchangeably in determining whether an invention offers a ‘substantial’ utility. ... Simply put, to satisfy the ‘substantial’ utility requirement, an asserted use must show that that claimed invention has a *significant and presently available benefit to the public*.” (Emphasis supplied.)

## **§ 101(d) – Additional Limitations and Exceptions Barred**

New § 101(d) expressly overrules all judicially imposed exceptions to subject matter that is eligible for patenting. This includes the implicit exception that has been heretofore applied by the courts under the Supreme Court’s *Mayo v. Prometheus*<sup>7</sup> and *Alice v. CLS Bank*<sup>8</sup> decisions and the two-part test used to implement it.

In the regard, the codified requirements for patent eligibility set out in § 101(a), § 101(b), and § 101(c) represent a complete substitute for—and are thus able to supersede—any non-statutory patent-eligibility requirements. In this regard, the § 101(d) bar to non-statutory patent-eligibility limitations is inherently premised on the ability of the remaining § 101 provisions to address any possible policy or constitutional concerns over legislatively abrogating the implicit exception and its implementing jurisprudence.

The policy justification for legislatively overruling the Supreme Court patent-eligibility precedents is, therefore, fundamentally grounded on a recognition that the new patent-eligibility requirements under §§ 101(a)-(c)—taken together with the other statutory conditions and requirements for patentability under 35 U.S.C. §§ 102, 103, and 112—should eliminate any realistic possibility that a patent claim meeting such requirements could be fairly regarded as being directed to a natural law or phenomenon or other abstract concept. Nor could such a valid patent claim preempt, prevent, or otherwise preclude access to the underlying/associated abstract concept given all §§ 101, 102, 103, and 112 requirements have been met.

This means that patent claims meeting all statutory requirements should not require any additional constitutional- or policy-driven patent eligibility bar to assure the proper functioning of the patent system consistent with the constitutional directive to promote the useful arts.

## **Conforming Amendments to Title 35 and the America Invents Act**

In addition to the amendment to § 101, three conforming amendments are made to the patent laws. First, the preamble to 35 U.S.C. § 102(a) is amended in light of the new § 101(a)’s right to patent provisions. This amendment to § 102(a) prevents possible confusion between § 101’s right-to-patent provisions and similar right-to-patent language currently presently in § 102(a). It also provides a more apt chapeaux for § 102(a) (*i.e.*, one ensuring a proper antecedent for the use of the term “claimed invention” therein).

Second, several provisions of law are repealed because they relate to claimed inventions that cannot meet the new field-of-technology limitation under § 101(a) and, therefore, moot the need for such provisions. The repealed provisions are 35 U.S.C. § 287(c) (relating to non-technological medical and surgical procedures) and § 14 and § 33 of the America Invents Act (relating respectively to patents relating to tax strategies and human organisms).

Third, several technical amendments are made to the transitional program for covered business method patents under the America Invents Act. For patents subject to amended § 101,

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<sup>7</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

<sup>8</sup> *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S. Ct. 2347, 2354 (2014).

the term “technological inventions” is defined to mean claimed inventions meeting the patent eligibility requirements under amended § 101. In addition, the USPTO’s “technological invention” implementing regulations are made inapplicable. Finally, the rule of construction relating to the foregoing is likewise rendered inapplicable.

### **Effective Date and Effect**

The above amendments to the patent laws will take effect six months following enactment and apply to all patents and pending applications for patent, except that they will not apply to deciding invalidity defenses in civil actions filed before six months after the effective date. In addition, the new eligibility standard will not apply to invalidate patents issued earlier than six months after the date of enactment that would have been valid had new § 101 not been enacted. Lastly, an application for patent filed after the date of enactment and pending sixth months after the date of enactment is afforded a three-month period in which the patent applicant may opt-out of the new standard under new § 101 by written notice to the Director.

### ***Policy Rationale for the Prototype “Field of Technological” Limitation Proposal***

The amendment to § 101 strikes a balance among differing views within various constituencies within the patent community—and the general public—on the subject matter that ought to qualify as eligible for patenting. The balance is in part reflected in the acknowledgement (implemented through a new “field of technology” limitation) that patent eligibility should not extend to non-technological medical and surgical procedures and business concepts, as well as tax and estate planning strategies and human organisms.

The § 101 amendment does so by barring patents for inventions that do contribute to any of the useful arts. On the other hand, the § 101 amendment furthers the core principle that patents should be broadly available otherwise for inventions in all fields of technology, without restriction or limitation.

Further reflecting this balance, the amendment rejects an unfettered and absolute application of the so-called “anything under the sun made by man” principle of patent eligibility. In contrast, the new statutory requirement, in effect, forges a middle ground under which patent-eligible inventions must contribute to a field of technology. This limitation derives directly from constitutional constraint that exclusive rights under the patent laws should exist to promote progress in the *useful arts*, *i.e.*, contribute to some field of *technological endeavor*.

To this end, the amendment reflects a broad consensus that patents directed to mere concepts, whether natural laws or phenomena or other abstract concepts, should be barred. The amendment to § 101 does so in explicit terms for such subject matter.

At the same time, it acts on an equally broadly held concern that the courts’ existing “implicit exception” jurisprudence has gone too far in barring patents that relate to abstract concepts—well beyond any patent-limiting rules in effect in other industrialized countries. It, therefore, overrules this exception.

While the § 101 amendment overrules all non-statutory limitations on patent eligibility (including the implicit except and the two-part test used by the courts to implement it), the new statute does not go so far as to accept the contention that no new patentability requirements are needed to substitute for overruling judicial the implicit exception. The simple abrogation approach—overruling the judicial implicit exception, but enacting no further statutory limitations on patent eligibility to replace it on the ground that addition of new statutory patent-eligibility requirements is not needed<sup>9</sup>—is rejected.

The amendment’s rejection of a simple abrogation approach is not based on any constitutional or policy considerations or on a rejection of the rationale supporting a simple abrogation. Rather, the simple abrogation approach would necessarily leave untouched provisions already in the patent statute limiting the availability of patent rights relating to non-technological medical/surgical procedures, tax/estate planning strategies, covered business methods (and other non-technological business concepts), and human organisms. By introducing a new field-of-technology limitation, these piecemeal efforts at limiting patent rights in specific subject matter areas can be superseded through a principle of general applicability limiting the availability of patents.

The justification for enacting new statutory limitations in any amendment to § 101 abrogating the implicit exception and its two-part test also takes account of the views of those who support continuing the existing Supreme Court jurisprudence. They see no compelling reason for any legislative intervention. From their vantage point, the Supreme Court’s precedents form an antidote for the wide-ranging use of the patent system to seek patents on subject matter such as business concepts. They assert that historically patents were seldom, if ever, secured for such non-technological subject matter. These critics point to the effects of the 1998 *State Street Bank* decision, as triggering an explosion in efforts to secure such patents.

The *field of technology* limitation serves to address the concerns of those who otherwise might urge that the judicial status quo be maintained. Such concerns have little residual vitality once patenting is limited to inventions that contribute to a field of technology.

The competing considerations above point to the desirability for Congress to address such concerns in a simple, but comprehensive manner. Doing so would require Congress to identify, if at all possible, broadly unifying principles for limiting patents that can obviate the need to respond to future pressures for more individual legislative limitations on patent rights addressing one subject matter area at a time.

The optimal principle for defining the availability of patent rights would have the promise of sufficiently broad applicability such that it might supersede the existing piecemeal legislative restrictions on patent rights that currently are part of the patent laws, as well as

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<sup>9</sup> The proponents of a simple abrogation of the implicit exception rely on arguments that the remaining statutory requirements for patentability fully address any constitutional and policy concerns that might be cited by the courts to justify continuing the implicit exception or its two-part test. Thus, in their view, nothing in overruling the implicit exception supports the need for the concomitant enactment of any new statutory restrictions on patent eligibility. See Brief of Eli Lilly and Company, *et al.*, in Support of the Petitioner in *Sequenom, Inc. v. Ariosa Diagnostics, Inc., et al.*, App. No. 15-1182, (*cert. den.*, June 27, 2016) (available at <http://www.scotusblog.com/wp-content/uploads/2016/04/15-1182-Amicus-Brief-of-Eli-Lilly-et-al..pdf>).

preempt future calls for such restrictions. Again, a *field of technology* limitation holds the promise of being able to do so.

Additionally, efforts to impose new patent-eligibility requirements should not be undertaken in a vacuum. The other important consideration driving the nature of any amendment to § 101 relates to U.S. treaty obligations and to international harmonization opportunities. The prime driver of the first of these two considerations is the U.S. obligations under the TRIPS Agreement. These TRIPS obligations require the United States to make patent rights available and enjoyable in all fields of technology—and without discrimination among the various fields of technology. These considerations, again, point in the direction of making a *field of technology* limitation an explicit statutory eligibility requirement.

As for the harmonization-related concerns, one prime consideration arises from the European Patent Convention that specifies “European patents shall be granted for any inventions, in *all fields of technology*, provided that they are new, involve an inventive step and are susceptible of industrial application.”<sup>10</sup> This provision of the EPC provides a motivation for identifying an eligibility limitation in the United States that is not unnecessarily inconsistent with the European “field of technology” restriction on patent eligibility.

Yet another consideration relevant to any new statutory provision on patent eligibility is the expressed goal of several constituencies affected by the patent system to preserve the ability to use the patent eligibility issue as a threshold inquiry in the determination of unpatentability.<sup>11</sup> Such constituencies assert that overruling of the implicit exception and its two-part test would be highly problematic unless accompanied by some new limitation on patent eligibility that would be similarly amenable to summary resolution (*i.e.*, adjudication prior to considering other, more nuanced patentability requirements). In this regard, the assessment of whether a claimed invention contributes to a field of technology is asserted by its proponents to be a question of law readily amenable to a threshold analysis.

Finally, several alternatives to the “field of technology” approach for limiting patent eligibility have been advanced as means for legislatively remedying the implicit exception in a manner to replace (or otherwise obviate the application of) the two-part test used to implement it. Critics of these alternative proposals have insisted that they contain fatally defective aspects.

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<sup>10</sup> European Patent Convention, Article 52.1

<sup>11</sup> *OIP Technologies, Inc. v. Amazon. com, Inc.*, 788 F. 3d 1359, 1364-1365 (Fed. Cir. 2015), “Failure to recite statutory subject matter is the sort of ‘basic deficiency,’ that can, and should, ‘be exposed at the point of minimum expenditure of time and money by the parties and the court,’ *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) (citations and internal quotation marks omitted). Addressing 35 U.S.C. § 101 at the outset not only conserves scarce judicial resources and spares litigants the staggering costs associated with discovery and protracted claim construction litigation, it also works to stem the tide of vexatious suits brought by the owners of vague and overbroad business method patents. Accordingly, where, as here, asserted claims are plainly directed to a patent ineligible abstract idea, we have repeatedly sanctioned a district court’s decision to dispose of them on the pleadings. See, *e.g.*, *Content Extraction & Transmission LLC v. Wells Fargo Bank*, 776 F.3d 1343, 1349 (Fed.Cir.2014); *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 717 (Fed.Cir. 2014); *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350, 1352 (Fed.Cir.2014). I commend the district court’s adherence to the Supreme Court’s instruction that patent eligibility is a ‘threshold’ issue, *Bilski v. Kappos*, 561 U.S. 593, 602, 130 S.Ct. 3218, 177 L.Ed.2d 792 (2010), by resolving it at the first opportunity.”

For example, one such proposal would nominally leave the two-part test in place, but legislatively mandate that the test would be satisfied whenever a claimed subject matter constitutes a practical embodiment or application of any natural law or phenomenon or other abstract concept on which the claimed invention is based or to which it otherwise relates. This test appears on its face to merely duplicate the existing § 101 requirement that valid patent claim be limited to a practically useful process, machine, manufacture, or composition of matter, *i.e.* a practically useful embodiment or application of any abstract concept associated with the claimed subject matter.

In contrast, if this “practical application or embodiment” standard does impose some additive requirement not currently present in existing § 101, the proponents of this approach have offered no indication of what simple, objective, administrable standard might be used to identify the otherwise patentable subject matter that this test would make unpatentable. In this regard, under a worst-case reading of this standard, it could be interpreted as merely a codification of the existing law that valid patent claims cannot be directed to abstract concepts unless they claim significantly more than the concept itself, specifically some inventive concept. Unless read as simply codifying existing statutory § 101 requirements, nothing in the “practical embodiment or application” standard is necessarily inconsistent with judicially administering it through the existing two-way test.

A second proposal purports to overrule the “implicit exception” (and the two-part test implementing it) by substituting a statutory requirement that would render claims unpatentable to the extent the claimed subject matter exists in nature independently of, and prior to, any human activity, or exists solely in the human mind. Critics of this proposal have offered a similar set of observations on its merits.

The proposed “human activity” requirement appears to be a mere duplicate of the existing statutory requirement under § 101 that inventions must be “new” in order to be patentable. If some additional novelty test is intended under the “human activity” standard, the proponents have offered no indication of what simple, objective, administrable standard might be used to identify the otherwise patentable subject matter that this test would make unpatentable.

The test’s second requirement that bars patent eligibility for subject matter existing entirely in the human mind has been criticized on precisely the same grounds as the test’s “human activity” requirement. Among other issues, it is unclear how a claimed invention so limited could ever be deemed practically useful as required under existing § 101.

In looking holistically at the concerns over the current state of § 101 jurisprudence and the myriad of competing constitutional, policy, treaty, economic, and even philosophical considerations that must be part of any legislative effort to define by statute what should constitute an invention eligible for patenting, the approach that appears to weave through the obstacles to finding a broadly based consensus is one that assures issued patents promote progress in the useful arts by confining valid patent claims to subject matter that *contributes to a field of technology*, without limitation or restriction, and further provides that the discovery of a natural law or phenomenon or other abstract concept, by itself, makes no such contribution.

Such an approach permits Congress to replace a much criticized and highly problematic judicial framework for limiting patent eligibility with a far more administrable statutory test. The policy objectives sought to be accomplished through the implicit exception and two-part test would not only be better served through such new § 101 requirements, but such amendments to the patent statute would further advance the overarching objective of creating a more transparent, objective, predictable, and simple patent law.

### ***Conclusions***

The above legislative prototype, and the discussion that accompanies it, is offered as a possible guide to understanding—and constructively working through to a political consensus—the thorny issues of patent eligibility. As Congress looks to settle on a single path forward for addressing the problematic aspects of the existing jurisprudence on patent eligibility, the above analysis suggests a principled (and intentionally balanced) middle ground. It is a middle ground nonetheless aimed at maintaining a strong patent system, with all the characteristics of an effective property rights system able to attract the investments needed to develop and market new technologies.

To those ends, the work product above offers what, upon further vetting, might prove to be an optimal framework for limiting patent eligibility. The suggested approach above is guided by constitutional principles. The prototype proposal offered above would accomplish what most urgently needs to be accomplished: *to entirely eliminate the judicial framework currently used to determine if subject matter is implicitly excepted from patent eligibility under § 101*. Lastly, in its place, a new statutory patent-eligibility standard is offered that does no less than assure patent rights would be available in all fields of technology, without restriction, without limitation, and without discrimination.

## APPENDIX B

### SEQUENOM V. ARIOSIA BRIEF FOR AMICI CURIAE ELI LILLY AND COMPANY, EISAI INC., UPSHER-SMITH LABORATORIES, INC., PFIZER INC., AND ETIOMETRY, INC. IN SUPPORT OF PETITIONER

#### QUESTION PRESENTED

The Patent Act contains a set of statutory patentability requirements. In addition to these statutory requirements, the Court has imposed a non-statutory “implicit exception” to patentability. This implicit exception was judicially imposed in part to assure that patents cannot be granted for concepts—or afford exclusive rights that may dominate or otherwise preempt access to concepts. *Concepts*, in this sense, refer to *laws* of nature, natural *phenomena*, or *ideas*, including abstract ideas. The implicit exception similarly bars patents directed or relating to *natural products* and entirely *mental processes*.

The Court has applied the implicit exception as part of a “threshold test” for patentability that operates before other patentability requirements may be considered. The exception, however, does no more than duplicate the statute’s effects when statutory provisions would also invalidate the same patent.

As a threshold test, it has not taken account of the manner in which today’s statutory requirements have evolved to fully address any policy justification for maintaining the exception. When other patent-limiting laws fully vindicate the policies that underlie the implicit exception, judicial restraint might demand outright abrogation of the exception.

*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?*

#### II. SUMMARY OF THE ARGUMENT

The Patent Act contains a set of statutory patentability requirements limiting the subject matter that valid patent claims can protect. In addition to these explicit requirements set out in the statute, the Court has imposed a non-statutory “implicit exception” to subject matter that can be validly patented. The implicit exception was imposed to assure that patents cannot validly protect—or preempt access to—laws of nature, natural phenomena, or abstract ideas.

The implicit exception operates as part of a “threshold test” for patentability that is to be applied before consideration is given to other patentability requirements. Whenever so applied, it precludes consideration of the explicit statutory requirements that might also have invalidated the same patent claims and it fails to account for the manner in which today’s statutory requirements fully address any policy justification for maintaining the implicit exception. If this exception operates today to accomplish nothing more than to invalidate patent claims that are otherwise invalid under the explicit statutory criteria, then judicial restraint may dictate that the implicit exception be abrogated because no justification for it would remain.

Today, explicit statutory provisions of the contemporary Patent Act found in 35 U.S.C. §§ 101, 102, 103, 112(a), 112(b), and 112(f) serve to preclude securing a valid patent on the

same subject matter that the policy justification for the implicit exception sought to bar from patenting. Therefore, the Court should now consider abrogating the implicit exception in deference to the explicit patentability requirements that Congress imposed.

### III. ARGUMENT

The Court has long applied an implicit exception to patent eligibility, irrespective of whether a patent for an invention would be valid under the statutory requirements for patentability.<sup>1</sup> Recent decisions implementing this jurisprudence have come under harsh criticism.<sup>2</sup> The most pointed criticism of the Court's implicit exception is that the Court's recent jurisprudence has expanded the reach of the exception such that today it applies to invalidate U.S. patents that would be clearly eligible for patenting under international norms.<sup>3</sup>

Other criticisms of the Court's recent jurisprudence have centered on the mechanics of the analysis that the Court has established for determining if a claimed invention in a patent is to be rendered invalid because it is directed to a law of nature, natural phenomenon, or abstract idea.<sup>4</sup> The current analysis consists of two steps. First, it requires a distillation of the claimed invention to establish whether the claim to the invention is based upon an underlying concept and, if so, whether the claim adds significantly more to the concept—namely some “inventive concept”—to qualify the invention for patenting.<sup>5</sup> While its generalized nature serves to blunt patent drafting techniques that otherwise might circumvent a bar to patents dominating concepts,<sup>6</sup> the result is a bar to patenting that is potentially wide ranging—since nearly all inventions have associated ideas upon which they are based.

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<sup>1</sup> “The Court has long held that [35 U.S.C. § 101] contains an important implicit exception. ‘[L]aws of nature, natural phenomena, and abstract ideas’ are not patentable.” *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012) (alteration in original). See also *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (“[M]ental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”) and *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013) (“[W]e hold that a naturally occurring DNA segment is a product of nature and not patent eligible.”).

<sup>2</sup> See, e.g., Bernard Chao, “USPTO Is Rejecting Potentially Life-Saving Inventions,” LAW360 (Dec. 18, 2014), available at <http://www.law360.com/articles/604808/uspto-is-rejecting-potentially-life-saving-inventions> (discussing the consequences of recent Supreme Court patent-eligibility decisions).

<sup>3</sup> See, e.g., Brief of Amicus Curiae Paul Gilbert Cole, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) (Nos. 2014-1139 and 2014-1144) at 10 (discussing the Federal Circuit panel's decision: “This case is an example of an internationally discordant, not harmonious, result, contrary to the eligibility requirements of TRIPS Article 27. Eligibility of the corresponding European patent was never disputed and it was held unobvious for solving the technical problem of detecting fetal nucleic acid with higher sensitivity, see EPO Appeal decision T 0146/07 *Prenatal diagnosis/ISIS*. It is wrong that a patent that survived obviousness challenge in Europe should be held ineligible in the U.S.”).

<sup>4</sup> See, e.g., Steven Seidenberg, “New Laws of Nature Law: Ruling Questions Scientific Patents,” ABA JOURNAL (Jul. 1, 2012), available at [http://www.abajournal.com/magazine/article/new\\_laws\\_of\\_nature\\_law\\_ruling\\_questions\\_scientific\\_patents/](http://www.abajournal.com/magazine/article/new_laws_of_nature_law_ruling_questions_scientific_patents/) and Anthony S. Volpe & Jonathan Lombardo, “U.S. Supreme Court's ‘Alice’ Decision Opens a Rabbit Hole,” Intellectual Property, THE LEGAL INTELLIGENCER (Online) (Dec. 3, 2014), available at <https://advance.lexis.com/>.

<sup>5</sup> “We have described step two of [the implicit exception] 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 Int’l*, 134 S. Ct. 2347, 2355 (2014) (alterations in original) (quoting *Mayo*, 132 S. Ct. at 1294).

<sup>6</sup> “A claim that recites an abstract idea must include ‘additional features’ to ensure ‘that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].’” *Alice*, 134 S. Ct. at 2357 (alternations in original) (quoting *Mayo*, 132 S. Ct. at 1297).

The Court’s analytical framework is intended to operate as a surrogate for the broader policy question of whether a patent claim is so conceptual that rights under the patent might dominate or otherwise preempt access to a law or product of nature, a natural phenomenon, or an abstract idea.<sup>7</sup> The Court has expressed concerns that the assertion of such a patent claim, by impairing access to basic tools of science and technology, could impede, rather than promote, progress in the useful arts.<sup>8</sup>

Like many surrogate tests, it risks overreaching its policy objectives. This risk is magnified when the implicit exception is applied as a “threshold test.”<sup>9</sup> Not knowing if one or more of the remaining statutory patentability requirements would invalidate a patent claim, the tendency is to stretch the threshold test’s application to assure a potentially problematic claim is invalidated—lest such a claim might otherwise survive as valid under the explicit statutory requirements. Moreover, in applying such a non-statutory limitation as a threshold consideration, it inherently operates without considering whether or how the present, explicit statutory framework, taken as a whole, may operate to routinely invalidate conceptual patent claims.

Indeed, while 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.<sup>10</sup> 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.

#### **A. Explicit Statutory Patentability Requirements Prevent Valid Patents From Protecting A Law Of Nature, Natural Phenomenon, Or Abstract Idea.**

##### **1. 35 U.S.C. § 101 Requires That Valid Patent Claims Must Be Limited To Applications—In The Form Of Physical Embodiments—Of Any Concept To Which A Patented Invention Relates.**

The Patent Act bars patentability of an invention not claimed as an *application* of any concept to which the invention relates because valid patent claims must be expressed in terms of the *physical embodiments* of the invention. Thus, the Patent Act by itself leaves no possibility for a valid patent claim to be directed to a law, phenomenon, or idea *as such*. The foregoing limitations on patenting arise under explicit provisions in 35 U.S.C. § 101.

Section 101 requires that a valid claim must be drafted in terms of a “process, machine, manufacture, or composition of matter” or an improvement thereto.<sup>11</sup> The statutory limitation on

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<sup>7</sup> “[T]he Court’s precedents . . . warn us against upholding patents that claim processes that too broadly preempt the use of a natural law.” *Mayo*, 132 S. Ct. at 1294.

<sup>8</sup> “[M]onopolization of [the basic tools of scientific and technological work] through the grant of a patent might tend to impede innovation more than it would tend to promote it.” *Id.* at 1293.

<sup>9</sup> *Bilski v. Kappos*, 561 U.S. 593, 602 (2010).

<sup>10</sup> “[T]he § 101 patent eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap. But that need not always be so. And to shift the patent eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.” *Mayo*, 132 S. Ct. at 1304.

<sup>11</sup> Patent Act of 1952, Ch. 950, 66 Stat. 792 (July 19, 1952); 35 U.S.C. § 101.

patenting to these four categories has remained essentially unchanged since the 1793 Patent Act, when Congress provided that patents would be available only for “any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter . . . .”<sup>12</sup>

When the words “machine, manufacture, or composition of matter” were used by Congress in the 1793 Patent Act, there can be no doubt that they referenced physical *things*. Moreover, to the extent an invention might be based upon an idea or other concept, the machines, manufactures, or compositions of matter were the things that *physically embodied* such concepts.

The same is the case for an “art” or “process.” As applied to patenting, the earliest definition of the statutory term “process” offered in a decision of the Court set out a like notion of physicality— “[a] process is a mode of treatment of certain materials to produce a given result. It is an *act*, or a *series of acts*, performed upon the subject-matter to be transformed and reduced to a different state or thing.”<sup>13</sup> The *act* or *acts* constituting a “process” under the patent law were, thus, of a like physical nature to the other statutory categories.”<sup>14</sup> To perform a process under the patent laws means carrying out one or more *acts* that are the *physical embodiment(s)* of any idea or concept to which a process invention relates.

These four statutory categories, by forcing valid patent claims to be expressed in terms of the applications that physically embody an invention, represent subject matter that is mutually exclusive with respect to mere concepts—such as laws, phenomena, and ideas. Therefore, the § 101 requirement that claims be directed to a statutory category excludes any possibility for securing a valid patent for an associated concept rather than for its embodiments.

In sum, the patent statute explicitly limits patenting to physical embodiments, *things* and *act-based processes* that can only ever be *applications* of any related concept and can never be the concept itself. No reliance on an “implicit exception” is necessary to prevent patents from covering concepts *per se*.

The *application* requirement in § 101 is, however, merely one of several statutory provisions of the Patent Act that operate together for “distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.”<sup>15</sup> And, it is through these other requirements that the statute assures valid patent claims further distinguish between an invention’s concept and the patentable applications of such concepts—by confining valid patent claims to *inventive, practically useful* applications of any related concept.

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<sup>12</sup> Patent Act of 1793, Ch. 11, 1 Stat. 318-323 (February 21, 1793). 35 U.S.C. § 101 employs the term “process” in place of the word “art.” (“In the language of the patent law, [a process] is an art.” *Cochrane v. Deener*, 94 U.S. 780, 788 (1877)); 35 U.S.C. § 100(b) of the 1952 Patent Act defines the term “process” to mean “process, art, or method.”)

<sup>13</sup> *Cochrane v. Deener*, 94 U.S. at 788 (emphasis added).

<sup>14</sup> “The process requires that certain things should be done with certain substances, and in a certain order . . . .” *Id.*; see also *Tilghman v. Proctor*, 102 U.S. 707, 728 (1881) (stating that “[a] machine is a thing. A process is an *act*, or a *mode of acting*. The one is visible to the eye, — an object of perpetual observation. The other is a conception of the mind, *seen only by its effects* when being *executed or performed*.” (emphasis added)).

<sup>15</sup> *Alice*, 134 S. Ct. at 2355.

## 2. 35 U.S.C. §§ 103 and 112(a) Limit Valid Patent Claims To Inventive And Useful Applications Of Any Related Concept.

In *Hotchkiss v. Greenwood*, the Court held that the patent laws contained an implicit requirement that valid patent claims must be sufficiently *inventive*, in addition to meeting the then-existing statutory requirements.<sup>16</sup> In enacting 35 U.S.C. § 103 as part of the 1952 Patent Act, Congress superseded this implicit requirement with an explicit statutory requirement for non-obviousness; a valid patent cannot be granted if “the claimed invention as a whole would have been obvious.”<sup>17</sup>

In *Brenner v. Manson*, the Court interpreted the § 101 statutory requirement that a patented invention be “useful.”<sup>18</sup> The Court addressed “whether the practical utility . . . is an essential element in establishing a prima facie case for the patentability” of a claimed invention by holding that “substantial utility” was required for which “specific benefit exists in currently available form.”<sup>19</sup> The Federal Circuit has consistently applied the Court’s holding, further clarifying that the required *practical and substantial utility* must be fully enabled based upon the patent disclosure, *i.e.*, under 35 U.S.C. § 112(a).<sup>20</sup>

The contemporary statutory requirements under § 101, § 103 and § 112(a) together operate to limit valid patent claims to *inventive* and *practically useful applications* of any law, phenomenon, or idea to which a claimed invention relates. Thus, as demanded by this Court’s most recent “implicit exception” precedents, patent claims meeting these explicit validity requirements under the patent statute must be limited to subject matter that represents “significantly more” than any concept on which the invention is based.

While these various statutory provisions address whether valid patent claims can literally cover a law, phenomenon or idea, they do not necessarily foreclose resort to patent drafting techniques that might be used to craft valid patent claims preempting access to such concepts. Other statutory requirements under the contemporary patent statute do, however, bar an inventor from securing a valid patent claim that has been drafted as nothing more than an attempt to preempt access to a stated law, phenomena, or other idea.

### **B. Explicit Statutory Provisions Negate Drafting Techniques That Might Produce Valid Patent Claims Dominating A Law, Phenomenon, Or Idea.**

As noted above, the Court’s most recent jurisprudence makes clear that the prohibition against a valid patent dominating or otherwise preempting access for a law, phenomenon, or idea should not be evaded by patent drafting techniques.<sup>21</sup> Its justification rests in part on a drafting-related concern, *i.e.*, that “transformation [of an abstract idea] into a patent-eligible application requires ‘more than simply stat[ing] the [abstract idea] while adding the words ‘apply it.’”<sup>22</sup>

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<sup>16</sup> *Hotchkiss v. Greenwood*, 52 U.S. 248, 267 (1851).

<sup>17</sup> 35 U.S.C. § 103.

<sup>18</sup> *Brenner v. Manson*, 383 U.S. 519, 534 (1966).

<sup>19</sup> *Id.* at 520, 534-535 (1966).

<sup>20</sup> *See In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).

<sup>21</sup> The Court has observed that a mechanism is needed that is able to “provide practical assurance that the [claimed invention] is more than a drafting effort designed to monopolize the law of nature itself.” *Mayo*, 132 S. Ct. at 1297; *see also Alice*, 134 S. Ct. at 2358-359 (warning against making “the determination of patent eligibility depend simply on the draftsman’s art.”) (internal quotation marks omitted).

<sup>22</sup> *Alice*, 134 S. Ct. at 2357 (alterations in original) (quoting *Mayo*, 132 S. Ct. at 1294).

The Patent Act of 1952 contains two provisions that, if properly interpreted and applied, fully negate the potential effectiveness of such drafting techniques: § 112(a)<sup>23</sup> and § 112(f).<sup>24</sup>

### 1. The 35 U.S.C. § 112(a) “Written Description” Requirement Invalidates Patent Claims When The Patent’s Disclosure Fails To Sufficiently Describe What The Claimed Invention Is Rather Than What It Does.

In *O’Reilly v. Morse*,<sup>25</sup> 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.”<sup>26</sup> The patent failed to further identify what the invention was. The Court held such a claim could not possibly be valid under the statutory test requiring a sufficient description.<sup>27</sup>

Under the 1952 Patent Act, the requirement for such a sufficient description of a patented invention appears in § 112(a). It is commonly called the “written description” requirement. The Federal Circuit’s interpretation of the contemporary “written description” requirement aligns with *O’Reilly v. Morse*. Federal Circuit precedents require that the physical embodiments of each claimed invention or each element or other limitation<sup>28</sup> must be identified other than in conceptual terms, *i.e.*, other than in terms of the function that the invention or element or other limitation of the invention performs.<sup>29</sup> As in *O’Reilly v. Morse*, Federal Circuit precedents, such as *Ariad v. Lilly*, dictate that a valid patent claim cannot encompass all applications for performing a described function.<sup>30</sup> This statutory requirement, properly interpreted and applied,

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<sup>23</sup> “The specification shall contain a written description of the invention.” 35 U.S.C. § 112(a).

<sup>24</sup> “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.” 35 U.S.C. § 112(f).

<sup>25</sup> *O’Reilly v. Morse*, 56 U.S. 62 (1854).

<sup>26</sup> *Id.* at 112.

<sup>27</sup> *Id.* at 120 (stating “[a]nd 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.”).

<sup>28</sup> See *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336 (Fed. Cir. 2005), reh’g en banc denied, 433 F.3d 1373 (Fed. Cir. 2006). The patent claim at issue in *LizardTech* was a “combination claim” invalidated under the § 112(a) “written description” requirement because of the absence of claim limitations that were necessary to restrict the claim to subject matter for which the patent contained a sufficient description. Such combination claims “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.” P.J. Federico, *Commentary on the New Patent Act*, 75 J. PAT. & TRADEMARK OFF. SOC’Y 161, 186 (1993).

<sup>29</sup> See *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). The patent sought to protect insulin cDNA compounds, broadly with respect to all mammals and specifically with respect to humans. The patent, however, failed to identify the actual structure for human insulin cDNA or the structures for all mammalian insulin cDNA compounds. The patent’s description, because it was effectively limited to no more than the *concept* of the DNA compounds that could code for human and other mammalian insulin proteins (rather than the identification of actual substances themselves capable of doing so), was insufficient under § 112(a). “A written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula, [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *Id.* at 1568 (alteration in original) (citation omitted).

<sup>30</sup> In *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc), the Federal Circuit noted that the appealed “claims are . . . genus claims, encompassing the use of all substances that achieve the desired result of reducing the binding of NF- $\kappa$ B to NF- $\kappa$ B recognition sites.” *Id.* at 1341. In invalidating the claims under the § 112(a) “written description” requirement, the Federal Circuit noted that “[s]uch claims merely recite a

simply invalidates a claim seeking to encompass more than the applications of the law, specifically applications that are not identified in the patent in terms of what they are, but rather are characterized merely in terms of what they do.

The upshot of § 112(a) “written description” jurisprudence is that inventions that are claimed in terms of an application that is defined broadly enough to preempt a concept cannot be validly patented. Such a claimed invention would not have a sufficient description under the statute as interpreted in *Ariad v. Lilly*. Indeed, the application of the “written description” requirement in *Ariad* demonstrates how the *proper interpretation and application* of the “written description” requirement addresses the Court’s concern in *Mayo* that reliance on the § 112(a) requirement alone risks allowing a valid patent claim to preempt a law of nature and “impede future innovation.”<sup>31</sup>

For combination claims, which have multiple elements, the § 112(a) “written description” requirement operates synergistically with § 112(f). For patent claims found valid under § 112(a), § 112(f) then limits the scope of the functional aspects of claim elements that might otherwise result in valid patent claims preempting a related concept.

## **2. 35 U.S.C. § 112(f), Interpreted In A Manner Consistent With *Halliburton v. Walker*, Limits The Protection Available For Combination Claims To Structures, Materials, Or Acts Disclosed In The Patent.**

In *Halliburton v. Walker*,<sup>32</sup> the Court invalidated a patent that had been drafted using a common technique of setting out one or more of the discrete elements in a combination claim in terms of a “means for” (or, in the case of a process, a “step for”) carrying out a specified function. As in *O’Reilly v. Morse*, the Court reasoned that the patent specification could not adequately describe an invention covering every means to the end set out in the claim: “a patentee cannot obtain greater coverage by failing to describe his invention than by describing it as the statute commands.”<sup>33</sup> Because a “functional” element defined a point of novelty over the prior art, the Court invalidated the claim.<sup>34</sup>

Congress enacted § 112(f) under the 1952 Patent Act to limit what functional elements in a claim could cover. By limiting the protection afforded under such functionally-defined claims to the patent’s disclosed structures, materials, or acts, the claims could be valid notwithstanding the Court’s holding in *Halliburton*. When functionally-defined elements are so limited, the holding in *Halliburton* is superseded by § 112(f) since such “functional” elements cover only the patent’s disclosed “structure, material, or acts” (and their equivalents) for carrying out the function. If § 112(f) is properly interpreted, the ordinary rules of “claim construction,”<sup>35</sup> free from any “presumptions” based on the form of the claim,<sup>36</sup> should apply to determine if a claim element is merely a functional reference or if it defines a set of structures, materials or acts.

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description of the problem to be solved while claiming all solutions to it and . . . cover any compound later actually invented and determined to fall within the claim’s functional boundaries . . .” *Id.* at 1353.

<sup>31</sup> *Mayo*, 132 S. Ct. at 1304.

<sup>32</sup> *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946).

<sup>33</sup> *Id.* at 13.

<sup>34</sup> “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.* at 9.

<sup>35</sup> *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), *cert. denied*, 546 U.S. 1170 (2006).

<sup>36</sup> Federal Circuit precedents relating to the implementation of § 112(f) employ “presumptions” to determine whether a claim element is subject to the § 112(f) limitation. The presumptions are triggered based on

Hence, the combination of § 112(a) and § 112(f) forecloses the possibility that patent drafting techniques might secure protection over a concept to which an invention relates beyond the physical embodiments of the invention as set out in terms of the specific structures, materials, or acts disclosed in the patent. Properly applying these statutory provisions defining when a patent claim can be valid—and what a valid patent claim may cover—assures that valid patent claims cannot preempt access to any concept underlying the claimed invention.

### C. Patents Should Be Confined to Non-Conceptual Subject Matter Through Tying The “Mental Step” Doctrine To 35 U.S.C. § 112(f).

A key policy concern with patents relating to “abstract ideas” involves patents directed to business concepts, *i.e.*, so-called “business method” patents.<sup>37</sup> The Court has recently addressed these policy concerns, holding that certain “business method” patents might run afoul of the Court’s implicit exception barring patents that preempt access to a business concept, such as hedging.<sup>38</sup>

Process steps, especially in business methods, can be drafted in such broad terms that they are not tied to any particular substance or apparatus for performing the steps. For some steps drafted this way, no limitation in the claim will preclude the step from being performed entirely through human thought.<sup>39</sup> Claims drafted with steps that might be performed by doing nothing more than thinking are self-evidently not confined to the types of physical “acts”<sup>40</sup> to which a valid patent claim must be limited under the definition in *Cochrane v. Deener*.<sup>41</sup>

By their nature, claim steps drafted in terms general enough to be capable of being performed by mere thinking should be regarded as sufficiently conceptual in character that the claim may be invalid under *Halliburton* absent the applicability of § 112(f). Given that § 112(f) was enacted in part to supersede the applicability of *Halliburton* by cabining the reach of functional steps in patent claims, § 112(f)’s limitation should apply to such a mental step to the same extent that § 112(f) limits any other type of claim step expressed in terms of carrying out a specified concept rather than specified physical “acts” to which the claim is limited. Limiting such a step to covering only the corresponding physical “acts”<sup>42</sup> disclosed in the patent

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whether or not the words “means for” or “step for” themselves appear in a claim element. *See, e.g., Williamson v. Citrix Online, LLC*, 792 F.3d 1339 (Fed. Cir. 2015) (en banc). These precedents have the potential to elevate form over substance in a manner potentially inconsistent with the statutory language.

<sup>37</sup> *See, e.g.,* Julia Angwin, “‘Business Method’ Patents Create Growing Controversy,” THE WALL STREET JOURNAL (Oct. 3, 2000), available at <http://www.wsj.com/articles/SB97052967318492257>.

<sup>38</sup> This was, in fact, the defect in *Bilski v. Kappos*, 561 U.S. at 611-12.

<sup>39</sup> Each of the steps of the claims before the Court in *Bilski* were drafted in such a broad and conceptual manner that they constituted “mental steps,” such as “initiating a series of transactions” and “identifying market participants,” types of activities that—absent some further claim limitation—could be carried out mentally. *Id.* at 599.

<sup>40</sup> Examples of process steps limited to “acts” that exclude the potential for being performed mentally—can be found in the claims in *Diamond v. Diehr*, 450 U.S. 175, 180 n.5 (1981). Diehr’s claims, unlike *Bilski*’s, were determined to be patent eligible. Diehr’s process was defined by computer-limited steps, such as “repetitively calculating in the computer,” that precluded mental performance of the respective steps.

<sup>41</sup> 94 U.S. 780, 788 (1877). *See* the discussion in section III.A.1, *supra*, at 8.

<sup>42</sup> This exclusion of mental activities from the “acts” to which the claim step is limited under § 112(f) represents a construction of this subsection that is entirely consistent with the statutory text. The use in § 112(f) of the term “acts” as applied to process claims appears in conjunction with terms “structure” and “material” that apply to limit protection for claims directed to machines, manufactures, and compositions of matter. This juxtaposition suggests a common physicality among this trilogy of terms that supports the interpretation of § 112(f) as excluding human thought from qualifying as an “act.”

inherently eliminates the possibility that merely performing the step mentally would infringe the patent.<sup>43</sup>

In addition to this application of § 112(f) to process claims containing individual mental steps, the proper interpretation of § 112(f) provides a statutory basis for barring a valid patent claim from covering an entirely mental process. A claim reciting only mental steps would be limited under § 112(f) to the patent's disclosed non-mental acts for carrying out the respective steps or, if the patent disclosed no such non-mental acts, the claim would be invalid under the requirement for definiteness in claiming under 35 U.S.C. § 112(b).<sup>44</sup> In this manner, under § 112(b)/§ 112(f), valid patent claims covering entirely mental processes could not exist under the patent statute, thereby further mooted the need for any nonstatutory "implicit exception."

#### **D. Under The Statutory Novelty Requirement, Valid Patent Claims Cannot Cover Or Otherwise Preclude Access To Any Naturally-Occurring Subject Matter.**

The statutory novelty requirement under 35 U.S.C. § 102 bars the patenting of any subject matter that exists or operates in nature. In *Peters v. Active Mfg. Co.*, the 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."<sup>45</sup> For the purpose of applying "inherent anticipation" principles, it matters not whether a natural law or product or natural phenomenon was newly-discovered.<sup>46</sup> All such naturally-occurring subject matter necessarily exists prior to its discovery, thereby precluding the possibility that it could be validly patented. Any allegation that a law or product or phenomenon might infringe a patent claim would necessarily establish that the claim was anticipated under § 102. Thus, this doctrine prevents validly patenting any law or product of nature or natural phenomenon, even if newly-discovered.

In a similar manner, the 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.<sup>47</sup> Thus, any effort to draft a patent claim that would extend protection under a

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<sup>43</sup> Federal Circuit precedents, however, have yet to recognize the applicability of § 112(f) to claims containing mental steps. To date, the Federal Circuit has neither invalidated process claims containing a mental step under the rationale of *Halliburton* nor subjected such a claim step to the limitation under § 112(f). See *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1373 (Fed. Cir. 2011) (stating that "[m]ethods which can be performed entirely in the human mind are unpatentable not because there is anything wrong with claiming mental method steps as part of a process containing non-mental steps, but rather because...methods which can be performed *entirely* in the human mind are the types of methods that embody the 'basic tools of scientific and technological work' . . . ." (emphasis in original)).

<sup>44</sup> Under the reasoning of *Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946 (Fed. Cir. 2007), *cert. denied*, 552 U.S. 1039 (2007), and cases cited therein, the absence of corresponding "acts" disclosed in the patent, to which § 112(f) would necessarily limit the claim, serves to invalidate the claim under § 112(b) because the scope of protection under the claim would not be defined with reasonable certainty.

<sup>45</sup> *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889) (citation omitted). The Federal Circuit restated the above rubric as "[t]hat which would literally infringe if later in time anticipates if earlier than the date of invention." *Lewmar Marine, Inc. v. Bariant, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988).

<sup>46</sup> See *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) (stating that "recognition by a person of ordinary skill in the art . . . is not required to show anticipation by inherency.").

<sup>47</sup> 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 . . .").

patent to preempt access to any natural product or law or natural phenomenon would inherently fail the novelty condition for patentability under § 102. In order to be validly patented, any subject matter based upon or otherwise relating to a law or product of nature or natural phenomenon would need to be confined to a *novel, inventive, and practically useful application of such*—as the statute provides under § 101, § 102, § 103, and § 112(a).

In sum, “inherent anticipation” assures that patent rights cannot impair access to the basic tools of science or technology or in any other way impede the ability of the patent system to promote progress in the useful arts.

#### **E. The Court Should Abrogate The “Implicit Exception” In Deference to the Explicit Statutory Framework**

The statutory framework of the patent law has developed to fully address the policy rationale that led the Court to augment the statutory patentability requirements with its non-statutory “implicit exception.” Interpreting the current statutory provisions in a manner consistent with the Court’s precedents makes it impossible to identify any scenario under which a valid patent could provide protection for a law of nature, a natural phenomenon, or an abstract idea—either directly or through drafting techniques aimed at yielding a valid patent claim that might dominate or otherwise preempt access to such a law, product, phenomenon, or idea. The same applies with respect to patents relating to entirely mental processes and products of nature.

Given the manifest difficulties that the implicit exception presents to the proper functioning of the patent laws, the Court should address whether judicial restraint now dictates deference to the statutory framework.

### **IV. CONCLUSION**

The statutory framework of the patent law has developed to fully address the policy rationale that led the Court to augment the statutory patentability requirements with its non-statutory “implicit exception.” Given the manifest difficulties that the implicit exception presents to the proper functioning of the patent laws, the Court should address whether judicial restraint now dictates deference to the statutory framework.