

No. 15-1182

In the Supreme Court of the United States

SEQUENOM, INC.,

Petitioner,

v.

ARIOSIA DIAGNOSTICS, INC., ET AL,

Respondents

On Petition for Certiorari
To The United States Court Of Appeals
For The Federal Circuit

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

Steven P. Caltrider
James J. Kelley
Lilly Corporate Center
Eli Lilly and Company
Indianapolis, IN 46285

Robert A. Armitage
Counsel of Record
320 Seaview Court
Marco Island, FL 34145
raarmitage@aol.com
(703) 801-6334

April 1, 2016

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?

TABLE OF CONTENTS

QUESTION PRESENTED	i
TABLE OF CONTENTS	ii
TABLE OF AUTHORITIES	iv
I. INTEREST OF <i>AMICI CURIAE</i>	1
II. SUMMARY OF THE ARGUMENT.....	1
III. ARGUMENT	3
A. Explicit Statutory Patentability Requirements Prevent Valid Patents From Protecting A Law Of Nature, Natural Phenomenon, Or Abstract Idea.....	7
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.....	7
2. 35 U.S.C. §§ 103 and 112(a) Limit Valid Patent Claims To Inventive And Useful Applications Of Any Related Concept.	10
B. Explicit Statutory Provisions Negate Drafting Techniques That Might Produce Valid Patent Claims Dominating A Law, Phenomenon, Or Idea.....	11
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.	13
2. 35 U.S.C. § 112(f), Interpreted In A Manner Consistent With <i>Halliburton v. Walker</i> , Limits The Protection Available For Combination Claims To Structures, Materials, Or Acts Disclosed In The Patent.	16
C. Patents Should Be Confined to Non-Conceptual Subject Matter Through Tying The “Mental Step” Doctrine To 35 U.S.C. § 112(f).	18
D. Under The Statutory Novelty Requirement, Valid Patent Claims Cannot Cover Or Otherwise Preclude Access To Any Naturally-Occurring Subject Matter.	21
E. The Court Should Abrogate The “Implicit Exception” In Deference to the Explicit Statutory Framework	23
IV. CONCLUSION	24

TABLE OF AUTHORITIES

Cases

<i>Alice Corp. Pty. Ltd. v. CLS Bank Int’l</i> , 134 S. Ct. 2347 (2014)	4, 5, 9, 12
<i>Ariad Pharms., Inc. v. Eli Lilly & Co.</i> , 598 F.3d 1336 (Fed. Cir. 2010) (en banc).....	14, 15
<i>Ass’n for Molecular Pathology v. Myriad Genetics, Inc.</i> , 133 S. Ct. 2107 (2013)	3
<i>Bilski v. Kappos</i> , 561 U.S. 593 (2010)	5, 18, 19
<i>Biomedino, LLC v. Waters Techs. Corp.</i> , 490 F.3d 946 (Fed. Cir. 2007), <i>cert. denied</i> , 552 U.S. 1039 (2007)	21
<i>Brenner v. Manson</i> , 383 U.S. 519 (1966)	10
<i>Cochrane v. Deener</i> , 94 U.S. 780 (1877)	8, 19
<i>CyberSource Corp. v. Retail Decisions, Inc.</i> , 654 F.3d 1366 (Fed. Cir. 2011).....	20
<i>Diamond v. Diehr</i> , 450 U.S. 175 (1981)	19

<i>Gottschalk v. Benson</i> , 409 U.S. 63 (1972)	3
<i>Halliburton Oil Well Cementing Co. v. Walker</i> , 329 U.S. 1 (1946)	16, 17, 19, 20
<i>Hotchkiss v. Greenwood</i> , 52 U.S. 248 (1851)	10
<i>In re Fisher</i> , 421 F.3d 1365 (Fed. Cir. 2005).....	11
<i>In re Slayter</i> , 276 F.2d 408 (C.C.P.A. 1960)	22
<i>Lewmar Marine, Inc. v. Bariant, Inc.</i> , 827 F.2d 744 (Fed. Cir. 1987), <i>cert. denied</i> , 484 U.S. 1007 (1988)	21
<i>LizardTech, Inc. v. Earth Res. Mapping, Inc.</i> , 424 F.3d 1336 (Fed. Cir. 2005), reh’g en banc denied, 433 F.3d 1373 (Fed. Cir. 2006).....	14
<i>Mayo Collaborative Servs. v. Prometheus Labs., Inc.</i> , 132 S. Ct. 1289 (2012)	<i>passim</i>
<i>O’Reilly v. Morse</i> , 56 U.S. 62 (1854)	13, 14, 16
<i>Peters v. Active Mfg. Co.</i> , 129 U.S. 530 (1889)	21

<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (en banc), <i>cert. denied</i> , 546 U.S. 1170 (2006)	17
<i>Regents of the Univ. of Cal. v. Eli Lilly & Co.</i> , 119 F.3d 1559 (Fed. Cir. 1997), <i>cert. denied</i> , 523 U.S. 1089 (1998)	14
<i>Schering Corp. v. Geneva Pharms., Inc.</i> , 339 F.3d 1373 (Fed. Cir. 2003), <i>reh'g en banc denied</i> , 348 F.3d 992 (Fed. Cir. 2003)	22
<i>Tilghman v. Proctor</i> , 102 U.S. 707 (1881)	8
<i>Williamson v. Citrix Online, LLC</i> , 792 F.3d 1339 (Fed. Cir. 2015) (en banc).....	17
Statutes	
35 U.S.C. § 100(b).....	8
35 U.S.C. § 101	<i>passim</i>
35 U.S.C. § 102	<i>passim</i>
35 U.S.C. § 112(a).....	<i>passim</i>
35 U.S.C. § 112(b).....	2, 21
35 U.S.C. § 112(f)	<i>passim</i>

Patent Act of 1793, Ch. 11, 1 Stat. 318-323
(February 21, 1793) 7, 8

Patent Act of 1952, Ch. 950, 66 Stat. 792
(July 19, 1952)*passim*

Other Authorities

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/> 4

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> 3

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). 3

Julia Angwin, “‘Business Method’ Patents Create Growing Controversy,” THE WALL STREET JOURNAL (Oct. 3, 2000), *available at* <http://www.wsj.com/articles/SB97052967318492257> 18

P.J. Federico, Commentary on the New Patent Act, 75 J. PAT. & TRADEMARK OFF. SOC’Y 161 (1993).. 14

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/ 4

I. INTEREST OF *AMICI CURIAE*¹

Amici curiae Eli Lilly and Company, Eisai, Inc., Upsher-Smith Laboratories, Inc., Pfizer Inc, and Etimetry, Inc. (“*Amici*”) have a strong interest that U.S. patent laws be interpreted to protect innovation to the fullest possible extent, consistent with the rigorous conditions and requirements for patenting Congress has legislated. *Amici* have grave concerns that invalidating patent claims that clearly meet international norms for patent-eligible subject matter, as the appellate court did below, profoundly undermines the core function of the patent system to provide reliable incentives to translate inventions and discoveries into innovations—products and services that can be of great benefit to humanity.

Amici have no financial interest in the parties to this litigation or in the outcome of this specific case.

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 patent-

¹ This brief was not authored, in whole or in part, by counsel for any party. No person or entity other than *Amici curiae*, their members, and their counsel made a monetary contribution to the preparation or submission of this brief. Counsel of record for each of the parties received timely notice of the intent to file this brief. Each party filed a blanket consent for all *amicus* briefs.

ed. 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.² Recent decisions implementing this jurisprudence have come under harsh criticism.³ 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.⁴

² “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.”).

³ 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).

⁴ 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 detect-

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.⁵ 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.⁶ While its generalized nature serves to blunt patent drafting techniques that otherwise

ing 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.”).

⁵ *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/ 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/>.

⁶ “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).

might circumvent a bar to patents dominating concepts,⁷ the result is a bar to patenting that is potentially wide ranging—since nearly all inventions have associated ideas upon which they are based.

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.⁸ 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.⁹

Like many surrogate tests, it risks overreaching its policy objectives. This risk is magnified when the implicit exception is applied as a “threshold test.”¹⁰ Not knowing if one or more of the remaining statutory patentability requirements would invalidate a patent claim, the tendency is to stretch the threshold

⁷ “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).

⁸ “[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.

⁹ “[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.

¹⁰ *Bilski v. Kappos*, 561 U.S. 593, 602 (2010).

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.¹¹ 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.

¹¹ “[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.

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.¹² The statutory limitation on 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 im-

¹² Patent Act of 1952, Ch. 950, 66 Stat. 792 (July 19, 1952); 35 U.S.C. § 101.

provement on any art, machine, manufacture or composition of matter”¹³

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.”¹⁴ The *act* or *acts* constituting a “process” under the patent law were, thus, of a like physical nature to the other statutory categories.”¹⁵ To perform a process

¹³ 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.”)

¹⁴ *Cochrane v. Deener*, 94 U.S. at 788 (emphasis added).

¹⁵ “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 ef-*

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.”¹⁶ 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 applica-*

facts when being executed or performed.” (emphasis added)).

¹⁶ *Alice*, 134 S. Ct. at 2355.

tions of any related concept.

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.¹⁷ 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.”¹⁸

In *Brenner v. Manson*, the Court interpreted the § 101 statutory requirement that a patented invention be “useful.”¹⁹ 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.”²⁰ 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

¹⁷ *Hotchkiss v. Greenwood*, 52 U.S. 248, 267 (1851).

¹⁸ 35 U.S.C. § 103.

¹⁹ *Brenner v. Manson*, 383 U.S. 519, 534 (1966).

²⁰ *Id.* at 520, 534-535 (1966).

disclosure, *i.e.*, under 35 U.S.C. § 112(a).²¹

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

²¹ See *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).

for a law, phenomenon, or idea should not be evaded by patent drafting techniques.²² 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.’”²³

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)²⁴ and § 112(f).²⁵

²² 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).

²³ *Alice*, 134 S. Ct. at 2357 (alterations in original) (quoting *Mayo*, 132 S. Ct. at 1294).

²⁴ “The specification shall contain a written description of the invention.” 35 U.S.C. § 112(a).

²⁵ “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).

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*,²⁶ 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.”²⁷ 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.²⁸

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 ele-

²⁶ *O’Reilly v. Morse*, 56 U.S. 62 (1854).

²⁷ *Id.* at 112.

²⁸ *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.”).

ment or other limitation²⁹ 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.³⁰ 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

²⁹ 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).

³⁰ 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).

function.³¹ This statutory requirement, properly interpreted and applied, 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.”³²

For combination claims, which have multiple el-

³¹ 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-[κ]B to NF-[κ]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 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.

³² *Mayo*, 132 S. Ct. at 1304.

ements, 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*,³³ 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.”³⁴ Because a “functional” element defined a point of novelty over the prior art, the Court invalidated the claim.³⁵

³³ *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946).

³⁴ *Id.* at 13.

³⁵ “The language of the claim thus describes this most crucial element in the ‘new’ combination in terms of what it will do

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,"³⁶ free from any "presumptions" based on the form of the claim,³⁷ should apply to determine if a claim element is merely a functional reference or if it defines a set of structures, materials or acts.

Hence, the combination of § 112(a) and § 112(f) forecloses the possibility that patent drafting tech-

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.

³⁶ *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), *cert. denied*, 546 U.S. 1170 (2006).

³⁷ 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 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.

niques 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.³⁸ 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.³⁹

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

³⁸ 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>.

³⁹ This was, in fact, the defect in *Bilski v. Kappos*, 561 U.S. at 611-12.

being performed entirely through human thought.⁴⁰ 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”⁴¹ to which a valid patent claim must be limited under the definition in *Cochrane v. Deener*.⁴²

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 cabin- ing 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

⁴⁰ 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 trans- actions” and “identifying market participants,” types of activi- ties that—absent some further claim limitation—could be car- ried out mentally. *Id.* at 599.

⁴¹ 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 preclud- ed mental performance of the respective steps.

⁴² 94 U.S. 780, 788 (1877). See the discussion in section III.A.1, *supra*, at 8.

step to covering only the corresponding physical “acts”⁴³ disclosed in the patent inherently eliminates the possibility that merely performing the step mentally would infringe the patent.⁴⁴

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

⁴³ 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.”

⁴⁴ 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)).

such non-mental acts, the claim would be invalid under the requirement for definiteness in claiming under 35 U.S.C. § 112(b).⁴⁵ 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.”⁴⁶ For the purpose of applying “inherent anticipation” principles, it matters not whether a natural law or prod-

⁴⁵ 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.

⁴⁶ *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. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988).

uct or natural phenomenon was newly-discovered.⁴⁷ 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.⁴⁸ Thus, any effort to draft a patent claim that would extend protection under a patent to preempt access to any natural product or law or natural phenomenon 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

⁴⁷ 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.”).

⁴⁸ 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 . . .”).

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.

Respectfully submitted,

Steven P. Caltrider
James J. Kelley
Lilly Corporate Center
Eli Lilly and Company
Indianapolis, IN 46285

Robert A. Armitage
Counsel of Record
320 Seaview Court
Marco Island, FL 34145
raarmitage@aol.com
(703) 801-6334

April 1, 2016