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September 16, 2015

Hon. Michelle K. Lee
Under Secretary of Commerce
U.S. Patent and Trademark Office
Alexandria, Virginia
via email: 2014_interim_guidance@uspto.gov

Re: Testimony Responsive to the *July 2015 Update on Subject Matter Eligibility*
(Update; Request for Comments), 80 Fed. Reg. 45429 (July 30, 2015)

Dear Ms. Lee:

This *pro bono* testimony is specifically focused upon patent-eligibility of compositions of matter, particularly in the biotechnology and pharmaceutical area.

An important – and fatally flawed – feature of the captioned *Update* is its implicit suggestion that § 101 patent-eligibility can be determined independent of § 103, i.e., *without* a prior art search to determine “inventiveness” (as codified as § 103). This is a central theme of the monograph, PATENT ELIGIBILITY: LAW AND PRACTICE IN A STATE OF FLUX (September 16, 2015)(*attached*).

The “markedly different characteristics” discussion fails to consider the origins of the quoted terminology, and hence its significance ; *see* the Monograph at § X-E, “*Markedly Different Characteristics*” *Guidance* (pp. 128-29).

Respectfully submitted,

Hal Wegner

Harold C. Wegner

PATENT ELIGIBILITY: LAW AND PRACTICE IN A STATE OF FLUX*

Harold C. Wegner**

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I. OVERVIEW

This monograph focuses upon patent-*eligibility* of “compositions” and “manufactures” as defined in 35 USC § 101, and, particularly, the judicial *exceptions* to patent-eligibility. While exceptions to “processes” under Section 101 are also important, particularly to software innovations, the focus, here, is particularly on new compositions and the special relevance of the statutory exceptions to innovations in the fields of biotechnology and pharmaceuticals.

Section 101, here, deals with subject matter open to patenting that may otherwise be excluded from patent-eligibility unless it meets the standards of nonobviousness under 35 USC § 103, that prior to the 1952 Patent Act was considered the standard of an “inventive” feature. For example, a screw is an article of “manufacture” which is patent-*eligible*, but if a similar screw has been in public use before the invention, this patent-eligible invention lacks *novelty* and hence is denied a patent on the basis of lack of *patentability*.

Of particular concern at the present time is the guidance of Under Secretary Michelle K. Lee in her updated guidance on patent eligibility, the *July 2015 Update: Subject Matter Eligibility*, available under 2014 Interim Guidance on Subject Matter Eligibility (July 30, 2015), (herein: “Lee 2015 Guidance”),* which is considered at § X, *PTO Patent-Eligibility Examination Guidance*, which is preceded by the history of the law and judicial precedent.

* available at <http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0> at <http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0>

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To focus upon the statutory test for patent-eligibility is simple: Is a claimed invention within one of the four Section 101 statutory pigeonholes of patent-eligible subject matter? Is the invention a “process”? A “machine”? A “manufacture”? Or is it a “composition of matter”?

Each of the quoted categories is one of the four areas of patent-eligibility that has been a part of the statutory landscape of the patent law in the United States since the end of the eighteenth century.

What complicates the patent-eligibility determination is that the Supreme Court has carved out exceptions to patent-eligibility. Thus, an industrial process that otherwise qualifies as a statutory “process” for purposes of patent-eligibility may be *excluded* from patent-eligibility under judge made exceptions such as where the point of novelty of the process is an algorithm. Or, a biological product clearly is within the classic understanding of a statutory “process” yet modern Supreme Court precedent excludes certain subject matter from patent-eligibility.

The Supreme Court case law that has created the exclusions from patent-eligibility is largely based upon recent decisions, in particular, *Mayo v. Prometheus*, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), the *Myriad* case, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), and *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014). Particularly as to *dicta* not necessary to the holdings of these cases, it may no longer be sufficient for an invention involving an “abstract” element, or an element which is a product of “nature”, to pass *patent-eligibility* muster: A claim that clearly defines a novel combination where one element is an

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“abstract” feature or product of “nature” may well be *patentable* under the traditional tests of novelty, nonobvious and support under 35 USC §§102, 103, 112, but may lack patent-*eligibility* under 35 USC § 101.

This unstable situation is expected to last for *at least* a few years, given the highly negative treatment of the subject matter by the current Administration as manifested by the 2015 Lee Guidance. Whether and when patent-eligibility issues will be overcome – and to what extent – depends upon factors that cannot be clearly foreseen: Will the Federal Circuit gain a better understanding of patent-eligibility issues? Will the patent community provide better input through briefing at the court? Will scholars who *have* studied the issue such as Prof. Lefstin gain a wider audience? Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. 565 (2015). Will the court through *en banc* reconsideration of conflicting lines of case dealing with patent “preemption” remove this issue as basis for the current wave of denials of patent-eligibility?

Whether an invention may be patented or not has traditionally focused on a case by case basis whether the claimed subject matter is “inventive” (until 1952 under *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1850), or is “nonobvious” (under a 1952 statutory codification in 35 USC § 103 of the requirement for the presence of “invention”).

Nearly four hundred years ago in the seventeenth century Statute of Monopolies of 1623-24 patent-*eligible* subject matter was defined as being focused upon “new * * * manufactures”. With language little changed since the Patent Act of 1793, the current statutory definitions of patent-eligible subject matter have

remained substantially unchanged and are now carried forward as 35 USC § 101 in the *Leahy Smith America Invents Act* (2011): Statutory patent-eligibility covers “any new and useful process, machine, manufacture, or composition of matter, or ... improvement thereof.”

Since *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1850), the *patentability* issue has focused upon whether subject matter is “inventive” – or, since the 1952 Patent Act, whether the invention is nonobvious under 35 USC § 103. The question is often referred to under the pre-1952 case law standard to determine whether the claimed subject matter has an “inventive” feature.

A key issue today is whether subject matter possessing “invention” or an “inventive” feature is also patent-*eligible*, a subject that became a center-stage topic through the *Benson* case, *Gottschalk v. Benson*, 409 U.S. 63 (1972)(Douglas, J.), and *Parker v. Flook*, 437 U.S. 584 (1978): These cases judicially created *exceptions* to statutory patent-eligibility. The extreme view of *Benson* that the “secrets” of the products of “nature” should not be basis for patent-eligibility stem from *dicta* in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)(Douglas, J.), a case which received little attention for nearly twenty-five years until its author brought the case into the spotlight in his subsequent opinion in the *Benson* case.

The period of anti-eligibility of *Benson* and *Flook* was terminated for three decades in the *Chakrabarty* case, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), reinforced for software in the *Diehr* case, *Diamond v. Diehr*, 450 U.S. 175 (1981). Peace in the patent-eligibility valley continued for nearly thirty years following

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Chakrabarty and *Diehr*; in that entire period the Court granted *certiorari* in only one more patent-eligibility, but patent-eligibility was sustained in the *Ag Supply* case, *J.E.M. Ag Supply, Inc. v Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001).

Today, a dark patent-eligibility cloud hangs over the patent system through a series of cases denying patent-eligibility to a variety of technologies including the “abstract” components of software innovations in *Bilski v. Kappos*, 561 U.S. 593 (2010), and the later cases of *Alice v. CLS Bank*, *Mayo v. Prometheus*, and the *Myriad* case.

The pendulum denying patent-eligibility is still moving away from patent-eligibility on the wings of *dicta* in *Mayo v. Prometheus*: It is difficult to see the movement continuing any further than it has in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, ___ F.3d ___ (Fed. Cir. 2015): *Ariosa* is a poster child for the proposition that the patent-eligibility case law from the Supreme Court is out of control. The claim in *Ariosa* is to method which permits determining an unborn child’s DNA by testing a *mother’s* blood sample as opposed to the traditional, invasive sampling of amniotic fluid from the womb. There is no claim to the DNA nor to its use: The DNA is merely *identified* through this blood test. The claimed “method [detects] a paternally inherited nucleic acid of fetal origin performed on a [blood] sample from a pregnant female, [that] comprises [(a)] *amplifying a paternally inherited nucleic acid* from the [blood] sample[;] and[(b)] detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.”

How far back toward patent-eligibility will the pendulum swing?

And, it if does, when?

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A major and unpredictable factor is what role will the Patent Office play in actively seeking to limit the scope of *dicta* from the Supreme Court cases. At the moment, the picture is extremely bleak, given the highly anti-patentee 2015 Lee Guidance from the Under Secretary who leads the Patent Office – and is expected to do so until a new Administration takes over the White House in 2017.

Even with a more favorable climate from the Administration, the answers will to a great degree depend upon whether the Federal Circuit and the advocates appearing before that appellate body are able to decipher the past two hundred years of case law as well as remove aberrant lines of case law through *en banc* review. As a prime example of the fantasy world of patent-eligibility is the perpetuation of the mythology that the exceptions to patent-eligibility have a basis of “150 years” of *stare decisis* from both English and American precedent.

The mythology of this long period of *stare decisis* is keyed to the House of Lords opinion in *Househill Coal & Iron Co. v. Neilson*, Webster's Patent Cases 673 (1843), and American Supreme Court decisions in *Le Roy v. Tatham*, 55 U.S. (14 How.) 156 (1853), *subsequent proceedings with the same parties confirming validity of other claims*, 63 U.S. 132 (1859), *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1854), and the *Rubber-Tip Pencil* case, *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498 (1874).

“Cite bites” in the cases since *Bilski* cannot alter the fact that none of these nineteenth century cases has a *holding* standing for the proposition of any limitation to the scope of patent-eligible subject matter. That *Househill Coal* provides absolutely no basis for the proposition that English case law restricted the

scope of patent-eligibility is mythology. See Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. 565 (2015). Neither do modern case law interpretations of the American precedent square with contemporaneous analysis of the cases, such as from the leading mid-nineteenth century patent scholar-practitioner, George Ticknor Curtis, *A Treatise on the Law of Patents for Useful Inventions as Enacted and Administered in the United States of America*, § 166, pp. 152-53 (Boston: Little, Brown and Company)(3rd ed. 1867)(analysis of *O'Reilly v. Morse*). See also Adam Mossoff, *O'Reilly v. Morse*, George Mason University Law and Economics Research Paper Series (2014). The idea that there is a 150 year record of restrictions on patent-eligibility is a view economical with the truth as to the realities of the actual case law precedent. See § II, “150 Years” of *Patent-Eligibility Stare Decisis*.

The current era of patent-eligibility case law provides as a constant refrain the need to deny patents which, if granted, would “preempt” research. In other words, if a patent is granted on a basic idea, this would preempt follow-on research. This is completely antithetical to the views of the nineteenth century. “[W]here [the patented invention] is made or used as an experiment ... for the gratification of scientific tastes ... the interests of the patentee are not antagonized, the sole effect being of intellectual character But if the products of the experiment are sold ... the acts of making or of use are violations of the rights of the inventor and infringements of his patent.” Rochelle Cooper Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 Ariz. L. Rev. 457, 458 (2004) (quoting William C. Robinson,

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The Law of Patents for Useful Inventions § 898 (1890)). *See* § III, *Modern Mythology of a Research “Preemption.”*

From early in the nineteenth century starting with *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) (Story, J.) and continuing up through the creation of the Federal Circuit in the early 1980’s, it was well established that the patent right did not block the public from its right to experiment “on” a patented invention: The public was free to experiment *on* the invention to see how it operates, to make improvements or to design around the patented technology. *See* § III-A, *Story Right to Experiment “On” an Invention*. Yet, recent Supreme Court precedent has seized upon the idea that grant of a patent “preempts” research, so that fundamental inventions should be denied patent-eligibility under a theory parallel to (but independently developed) from the Federal Circuit line of case law. *See* § III-B, *Current “Research Preemption” Confusion*.

The incomplete understanding of the current Supreme Court of the fundamental right of the public to experiment “on” a patented invention is fueled by Federal Circuit abdication of its responsibility to create a uniform body of patent law that is historically accurate: The appellate court has left largely unscathed a line of panel precedent that is directly at odds with the fundamental right to experiment “on” a patented invention. Fuel for this aberrant line of precedent may be traced back to a trial court opinion in *Deuterium Corp. v. United States*, 19 Cl.Ct. 624 (Cl.Ct.1990)(Rader, J.), followed by *Embrex v. Service Eng’g*

Corp., 216 F.3d 1343 (Fed.Cir.2000) (Rader, J., concurring). See § III-C, *Deuterium Ghost at the Federal Circuit*.

In some situations a claimed combination has software as only *one element* of that combination so there is no preemption of that *element* through practice of the patented invention. The current wave of Supreme Court patent-eligibility cases is difficult to square with the *Adams Battery* case, *United States v. Adams*, 383 U.S. 39 (1966), where it is the overall combination that is evaluated as opposed to the individual elements. (To be sure *Adams Battery* dealt with patentability and not patent-eligibility.) See § IV, *Patent-Eligibility of the Claimed Invention*.

A major source of confusion today is the contemporaneous meaning given to legal terminology of the nineteenth century which has resulted in a conflation of patent *eligibility* and patentability. See § V, *Patent Eligibility and Patentability Conflation*. “Invention” or “inventive” activity in the century before the 1952 Patent Act became a patentability requirement commencing with the leading case, *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1850). *Hotchkiss* spoke of a requirement for “invention” which was codified as nonobviousness in the 1952 Patent Act. See § V-A, “*Inventive*” Subject Matter Prior to the 1952 Patent Act. In the century between the judicial creation of a test of “invention” up to the 1952 Patent Act, “invention” or “inventive activity” was the common way to refer to what is today a nonobvious invention. See § V-B, “*Inventive*” Subject Matter Prior to the 1952 Patent Act. *Funk v. Kalo* (1948) – just prior to the codification of the test of “invention” – stands out as of particular importance, simply because it has been cited so often. See § V-C, *Funk v. Kalo* “*Nature’s Secrets*” Dicta .

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The statutory test for nonobviousness plays an important role in the patent-eligibility discussions. See § VI, *The Graham Statutory Nonobviousness Inquiry*. Whether subject matter is or is not “inventive” or non-obvious must be focused on the four factor test under *Graham v. John Deere & Co.*, 383 U.S. 1 (1966). See § VI-A, *The Fact-Intensive Four Factor Graham Test*. A basic flaw in the *Mayo* scheme for analysis of an “inventive” step is that it does not follow the objective tests of the *Graham* case. See § VI, *The Graham Statutory Nonobviousness Inquiry*. The *Mayo* test for an “inventive” feature totally ignores the four part test laid down in the *Graham* case. See § VI-A, *The Fact-Intensive Four Factor Graham Test*. The seeds for the current era of confusion over patent-eligibility may be traced to a brief, less than ten year period two generations ago. See § VI-B, *Benson to Diehr (1972-1981)*.

With nearly forty years of peace in the patent-eligibility valley the current era of unrest commenced with the *Bilski* case. See § VI-C, *The Current Bilski Era (2010 - ____)*. The current era has seen a flurry of holdings against the inventor. See § VI-C, *The Current Bilski Era (2010 - ____)*.

No case had less direct relevance to patent-eligibility of a software or a natural product than *Mayo v. Prometheus* but no case has had broader impact on patent-eligibility confusion that reigns today than *Mayo v. Prometheus*. See § VI-C-1, *The Mayo “Step Two” Analysis*. Most problematic of all is the shortcut taken by the Court to bypass the four step *Graham* inquiry: the Court in *Mayo* considers generic software as an element to lack an “inventive” feature. See § VI-C-2, *The Rigid Mayo “Apply It” Test*. *Mayo* has since been carried forward in *Alice*. See § VI-C-3, *Alice, Mayo Déjà vu*.

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Remarkably, the Patent Office has cited as a basis to *deny* patent-eligibility keyed to out of context statements from *Chakrabarty*, a case where the standard of what is “inventive” was *not* an issue and where the degree of “inventive” activity was “markedly different”, a higher level of invention than the minimum standard. *See* § VII, *The Special Significance of Chakrabarty*.

Ariosa presents one of the most appealing cases both for *en banc* review as well as grant of *certiorari*. The high technology of the subject matter coupled with a total absence of any need to understand that technology to deal with the legal issues in the first instance makes this an attractive case. The extreme holding denying patent-eligibility trumps the attractive nature of the technology. There are at least three issues which the court *could* and at some point *should* grant *en banc* review to clarify the position of the court. *See* § VIII, *En Banc-Worthy Issues within Ariosa*.

The first issue of importance is whether there is a scope of subject matter where patent-eligibility is to be denied even though “inventive” or “nonobvious”. Five members of the court have answered the question in the affirmative by denying patent-eligibility to subject matter unless it possesses a “*significant* ‘inventive concept.’” *See* § VIII-A, “*Inventive*” *Subject Matter Lacking Patent-Eligibility*.

A second issue of great importance is the conflict between opinions that deny patent-eligibility to a claim based upon the lack of patent-eligibility of an element of the claim, standing alone, versus the well settled “all elements” rule that

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a claim should be considered *as a whole*. See § VIII-B, *Patent-Eligibility Keyed to the Invention As a Whole*

A *third* issue is the question whether “preemption” of research is a fundamental issue required for denial of patent-eligibility. See § VIII-C, *Research “Preemption” as Basis to Deny Patent-Eligibility*

Given the large number of issues raised in *Ariosa* and the widespread publicity the decision has gotten, now comes the immediate question: Should rehearing *en banc* be granted? See § IX, *Should Ariosa be Reheard En Banc?*

If the question is asked as to any one of the three *en banc*-worthy issues of the preceding section, the answer is a *conditional* yes. The condition is that the court is able to provide either a unanimous decision or one with very few dissents to create a solid precedent upon which the patent community can rely. In view of *Bilski* and other recent cases, this is a condition that cannot be taken for granted. See § IX-A, *Sua Sponte Consideration of Issues within the Ariosa Opinion*.

But, if the question is asked as to the issue presented in the petition, the answer should be an emphatic “no”: The issue presented suggests a conflict between the holdings of *Mayo*, *Alice* and *Ariosa* but the *holding* in each of the three cases is a denial of patent-eligibility. As to the *holdings* of each of the cases there is no conflict. Cf. FRAP 35(b)(1)(A), requiring that “[t]he petition must begin with a statement that *** the panel decision *conflicts* with a decision of the United States Supreme Court ****.”) See § IX-B, *Should the Petition for En Banc Review in Ariosa be Granted*.

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An immediate issue not directly tied to *Ariosa* is the flood of patent-eligibility denials at the Federal Circuit which are based upon a naked analysis of Section 101 *without* an examination for nonobviousness. *See* § X, *PTO Patent-Eligibility Examination Guidance*.

The PTO *should* totally scrap its current guidelines for Section 101 examination and, instead, deal with patent-eligibility at the *ex parte* examination stage with two rules: *First*, “inventive” subject matter should be determined by whether the claimed invention is nonobvious or not. *Second*, the nonobviousness determination should be based upon the claim *as a whole* with “all elements” and not dissected piecemeal. *See* § X-A, *What the PTO should due*. To be sure, the opportunity to challenge a patent for want of patent-eligibility should remain for post grant review proceedings. *See* § X-B, *Opportunity to Raise a Standalone Section 101 Issue*. The writer is not unmindful that under *Mayo* section 101 can be considered during patent litigation. *See* § X- C, *Honoring Supreme Court Rules for Patent Litigation*.

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The Lee 2015 Guidance has, if anything, set the system in a rear tailspin by focusing upon fact patterns in recent case law and providing bold instructions to the examining corps to essentially abandon traditional search and examination functions of the Office. Particularly dangerous is her bold instruction to the examining corps that it may abandon search and examination for an “inventive” or “nonobvious” feature. *See id.*, § IX-D, *PTO Abdication of its Basic Examination Function*. Also dangerous is the fact that she sets the bar for patent-eligibility to require “markedly different characteristics” for subject matter that may well be inventive without reaching this standard. *See* § IX-E, “*Markedly Different Characteristics*” *Guidance*.



II. “150 YEARS” OF PATENT-ELIGIBILITY STARE DECISIS

A succession of modern Supreme Court cases has incorrectly stated that the exceptions to patent-eligibility go back more than 150 years to cases that include *Househill Coal & Iron Co. v. Neilson*, Webster's Patent Case 673 (House of Lords 1843)), cited in *Le Roy v. Tatham*, 55 U.S. (14 How.) 156 (1853), as well as *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1854).

In the *Metabolite* dissent all three cases are cited for the proposition that the relevant principle of law that excludes from patent protection laws of nature, natural phenomena, and abstract ideas “finds its roots in both English and American law.” *Lab. Corp. of America Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126 (2006)(Breyer, J., joined by Stevens, Souter, JJ., dissenting from dismissal based on denial of certiorari).

In *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), citing, once again, the three cases, the opinion states that “[t]he Court has long held that [Section 101] contains an important implicit exception. ‘[L]aws of nature, natural phenomena, and abstract ideas’ are not patentable.”

Subsequent to *Mayo* in the *Myriad* case, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013), and *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014), the Court states that it has “interpreted § 101 and its predecessors ... for more than 150 years” to “ ‘contain[] an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable.’ ” *Alice*, 134 S. Ct. at 2354 (2014), quoting *Myriad*, 133 S.Ct. at 2116.

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Prior to *Bilski* the last Supreme Court holding denying patent-eligibility was in *Parker v. Flook*, 437 U.S. 584 (1978), which also employed the same mythology: “‘A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.’ *Le Roy v. Tatham*, [55 U.S. (14 How.) 156, 175 (1853)].

Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.” [*Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)].” *Parker v. Flook*, 437 U.S. at 589.

Federal Circuit has spoken of “*stare decisis* going back 150 years[.]” *Prometheus Laboratories, Inc. v. Mayo Collaborative Serv.*, 628 F.3d 1347, 1353 (Fed. Cir. 2010)(Lourie, J.)(citing *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 174-75 (1853)), *subsequent proceedings sub nom Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). “Prohibitions against patenting abstract ideas, physical phenomena, and laws of nature ‘have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years.’” *Myspace, Inc. v. Graphon Corp.*, 672 F.3d 1250, 1268 (Fed. Cir. 2012)(Mayer, J., dissenting)(quoting *Bilski v. Kappos*, 130 S.Ct. at 3226).

In fact, neither *Househill Coal*, *Le Roy v. Tatham*, *O’Reilly v. Morse* nor the *Rubber-Tipped Pencil* case compels a conclusion that there are exceptions to the scope of patent-eligibility, as discussed in the following section on *Househill Coal Nineteenth Century English Precedent* (referencing Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. 565, 594-96 (2015)).

A. Early English *Househill Coal* Case

Househill Coal & Iron Co. v. Neilson, Webster's Patent Case 673, 683 (House of Lords 1843)), is cited as foundation for *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853). See Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. 565, 594-96 (2015)(analyzing traditional notions of patent eligibility of newly discovered laws of nature); cf. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, ___ F.3d ___, ___ (Fed. Cir. 2015)(Linn, J., concurring)(“Sequenom's invention is nothing like the invention at issue in *Mayo* [*Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012)]. Sequenom ‘effectuate[d] a practical result and benefit not previously attained,’ so its patent would traditionally have been valid. *Le Roy v. Tatham*, 63 U.S. 132, 135-36 (1859)(quoting *Househill Coal & Iron Co. v. Neilson*, Webster's Patent Case 673, 683 (House of Lords 1843)); *Le Roy v. Tatham*, 55 U.S. 156, 175 [(1853)] (same); see generally Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. [565, 594-96 (2015)](analyzing traditional notions of patent eligibility of newly discovered laws of nature). But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.”).

See also *In re Bergy*, 596 F.2d 952, 991 (CCPA 1979)(Baldwin, J., concurring)(“A new property discovered in matter, when practically applied, in the construction of a useful article of commerce or manufacture, is patentable; but the process through which the new property is developed and applied, must be stated, with such precision as to enable an ordinary mechanic to construct and apply the necessary

process. This is required by the patent laws of England and of the United States, in order that when the patent shall run out, the public may know how to profit by the invention. It is said, in the case of the *Househill Company v. Neilson*, 1 Webs. Pat. Cas., 683, ‘A patent will be good, though the subject of the patent consists in the discovery of a great, general, and most comprehensive principle in science or law of nature, if that principle is by the specification applied to any special purpose, so as thereby to effectuate a practical result and benefit not previously attained.’ *Id.* at 174-5.”)

B. *Le Roy v. Tatham*, The Lead Pipe Case

Le Roy v. Tatham, 55 U.S. (14 How.) 156 (1853), states that:

“A new property discovered in matter, when practically applied, in the construction of a useful article of commerce or manufacture, is patentable; but the process through which the new property is developed and applied, must be stated, with such precision as to enable an ordinary mechanic to construct and apply the necessary process. This is required by the patent laws of England and of the United States, in order that when the patent shall run out, the public may know how to profit by the invention. *It is said, in the case of the Househill Company v. Neilson, Webster's Patent Cases, 683, 'A patent will be good, though the subject of the patent consists in the discovery of a great, general, and most comprehensive principle in science or law of nature, if that principle is by the specification applied to any special purpose, so as thereby to effectuate a practical result and benefit not previously attained.'"*

Le Roy v. Tatham, 55 U.S. (14 How.) at 175 (emphasis added). The emphasized portion of this opinion is repeated in *Le Roy v. Tatham*, 63 U.S. (22 How.) 132 (1859). *Le Roy v. Tatham* has nothing to do with an “abstract” idea.

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The invention involved was to a method of making a lead pipe.

A lead pipe!

George Ticknor Curtis, the leading patent scholar-practitioner at the time of *Le Roy v. Tatham*, 55 U.S. (14 How.) 156 (1853), provides a contemporaneous view of the case that demonstrates that the patentee essentially suffered from a case of bad claim drafting: “The case of *Le Roy v. Tatham*[, 55 U.S. (14 How.) 156 (1853),] resulted unfavorably to the patentees, by a construction of the claim which, if correct, shows that the real invention was not duly described in the claim itself. But in a subsequent proceeding (in equity), this patent again came before the Supreme Court, and appears to have been construed and sustained as a patent for a new *process*, which it undoubtedly was.” George Ticknor Curtis, *A Treatise on the Law of Patents for Useful Inventions as Enacted and Administered in the United States of America*, § 153, p. 135 n.1 (Boston: Little, Brown and Company)(3rd ed. 1867)(original emphasis). That the patentee’s lead pencil *was* directed to patentable subject matter was emphasized when the case returned to the Supreme Court several years later: “[The invention’s] application to the development and employment of a new property of lead made a new and patentable process. *See Le Roy v. Tatham*[, 63 U.S. (22 How.) 132 (1859)].” *Id.*

A detailed analysis of the case is provided by Professor Jeffrey A. Lefstin, *Inventive Application: A History*, 67 Fla. L. Rev. 565, 594-96 (2015). In contrast to the characterization of *Le Roy v. Tatham* since *Funk v. Kalo* nineteenth century case law more properly provides a more contemporaneous explanation of the case.

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A Supreme Court case from the same century, *Busell Trimmer Co v. Stevens*, 137 U.S. 423 (1890)(Lamar, J.). See also Professor Jeffrey A. Lefstin, *Inventive Application: A History*, 67 Fla. L. Rev. 565, 594-96 (2015). As explained in *Busell Trimer*:

In *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 177 (1853), ... the claim was for a combination of old parts of machinery to make lead pipes, in a particular manner, under heat and pressure. The combination was held not to be patentable, the court saying: 'The patentees claimed the combination of the machinery as their invention in part, and no such claim can be sustained without establishing its novelty, not as to the parts of which it is composed, but as to the combination.' The court also quoted, with approval, the following from *Bean v. Smallwood*, 2 Fed. Cas. 1142 (No. 1,173)(D. Mass. 1843), an opinion by Mr. Justice STORY: 'He [the patentee] says that the same apparatus, stated in this last claim, has been long in use, and applied, if not to chairs, at least in other machines, to purposes of a similar nature. If this be so, then the invention is not new, but at most is an old invention or apparatus or machinery applied to a new purpose. Now, I take it to be clear that a machine or apparatus or other mechanical contrivance, in order to give the party a claim to a patent therefor, must in itself be substantially new. If it is old and well known, and applied only to a new purpose, that does not make it patentable.'"

Busell Trimmer, 137 U.S. at 433-34.

Bean v. Smallwood is just one of several leading cases standing for the proposition that the application of an old process to a new use lacks patentable novelty. See *Dunbar v. Myers*, 94 U.S. 187, 199 (1876)(Clifford, J.)(citing *Howe v. Abbott*, 12 Fed. Cas. 42 (No. 6,766)(D. Mass. 1842)(Story, J.); *Bean v. Smallwood*, 2 Fed. Cas. 1142 (No. 1,173)(D. Mass. 1843); *Glue Co. v. Upton*, 97 U.S. 3 (1877))("Judge Story held, many years ago, that the mere application of an old process, machine, or device to a new use was not patentable,— that there must be some new process or some new machinery to produce the result, in order that the supposed inventor may properly have a patent for the alleged improvement."). See

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also *Brown v. Piper*, 91 U.S. 37, 41 (1875)(Swayne, J.)(citing, *inter alia*, *Howe v. Abbott and Bean v. Smallwood*)("[T]his was simply the application by the patentee of an old process to a new subject, without any exercise of the inventive faculty, and without the development of any idea which can be deemed new or original in the sense of the patent law. The thing was within the circle of what was well known before, and belonged to the public. No one could lawfully appropriate it to himself, and exclude others from using it in any usual way for any purpose to which it may be desired to apply it.").

As explained in *Diehr*, "[t]he question ... of whether a particular invention is novel is 'wholly apart from whether the invention falls into a category of statutory subject matter.'" *Id.*, quoting *Diamond v. Diehr*, 450 U.S. 175, 190 (1981), quoting *In re Bergy*, 596 F.2d 952, 961 (CCPA 1979)(Rich, J.).

To be sure, *Le Roy v. Tatham* is not the only case relied upon by the Court as basis for an exception to patent-eligibility. Other notable cases having nothing to do with patent-eligibility but instead deal with the nineteenth century invention of the eraser-tipped pencil, the *Rubber-Tip Pencil* case, *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498 (1874), and the more modern aggregation of several known species of microorganism in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

The *Rubber-Tip Pencil* case has been cited for "the longstanding rule that 'an idea of itself is not patentable.'" See *Diamond v. Diehr*, 450 U.S. at 164-65 (dictum)(citing *Rubber-Tip Pencil*, 87 U.S. (20 Wall.) at 507), and other cases for the proposition that "[t]his Court has undoubtedly recognized limits to § 101 and

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every discovery is not embraced within the statutory terms. Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas.’); *see also Parker v. Flook*, 437 U.S. at 598-99 (Stewart, J., joined by Burger, C.J., Rehnquist, J., dissenting)(citing *Rubber-Tip Pencil*, 87 U.S. (20 Wall.) at 507), and other cases for the proposition that ‘[i]t is a commonplace that laws of nature, physical phenomena, and abstract ideas are not patentable subject matter [under 35 USC § 101]. A patent could not issue, in other words, on the law of gravity, or the multiplication tables, or the phenomena of magnetism, or the fact that water at sea level boils at 100 degrees centigrade and freezes at zero –even though newly discovered.’”

The first two paragraphs of the opinion in the *Rubber-Tip Pencil* case make it crystal clear that it was *acknowledged* that the claimed rubber-tipped pencil *is* an “article of manufacture” (and hence to patent-eligible subject matter). But, the question presented was whether this new article of manufacture is *patentable* in the sense of what today are the patentability considerations of novelty and nonobviousness:

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“The question which naturally presents itself for consideration at the outset of this inquiry is, whether the new article of manufacture, claimed as an invention, was patentable as such. ...

“A patent may be obtained for a new or useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof. In this case..., [the] patent was for ‘a new manufacture,’ being a new and useful rubber head for lead-pencils. It was not for the combination of the head with the pencil, but for a head to be attached to a pencil or something else of like character. It becomes necessary, therefore, to examine the description which the patentee has given of his new article of manufacture, and determine what it is, and whether it was properly the subject of a patent.”

Rubber-Tip Pencil, 87 U.S. (20 Wall.) at 504-05.

Patentability was denied under classic principles of novelty and nonobviousness:

“But the cavity [of the claimed pencil] must be made smaller than the pencil and so constructed as to encompass its sides and be held thereon by the inherent elasticity of the rubber. This adds nothing to the patentable character of the invention. Everybody knew, when the patent was applied for, that if a solid substance was inserted into a cavity in a piece of rubber smaller than itself, the rubber would cling to it. The small opening in the piece of rubber not limited in form or shape, was not patentable, neither was the elasticity of the rubber. What, therefore, is left for this patentee but the idea that if a pencil is inserted into a cavity in a piece of rubber smaller than itself the rubber will attach itself to the pencil, and when so attached become convenient for use as an eraser?

“An idea of itself is not patentable, but a new device by which it may be made practically useful is. The idea of this patentee was a good one, but his device to give it effect, though useful, was not new.”

Rubber-Tip Pencil, 87 U.S. (20 Wall.) at 507.

The holding in the *Rubber-Tipped Pencil* case was to the product still in use today, the modern pencil pointed at one end with “lead” and eraser-tipped at the other, which was found invalid over the prior art under what today would be obviousness under 35 USC § 103.

C. The Real Story of *O’Reilly v. Morse*

O’Reilly v. Morse, 56 U.S. (15 How.) 62 (1854), is frequently cited by the Supreme Court as a basis for denying patent-eligibility. For example, in *Alice* the Court stated that “[w]e have ‘repeatedly emphasized th[e] . . . concern that patent law not inhibit further discovery by improperly tying up the future use of’ these building blocks of human ingenuity.” *Alice*, 134 S. Ct. at 2354 (quoting *Mayo*, citing *O’Reilly v. Morse*, 56 U.S. (15 How.) at 113).

Much of the discussion of this case is colored by applying current meanings to a different practice from a different era. See Adam Mossoff, *O’Reilly v. Morse*, George Mason University Law and Economics Research Paper Series (2014), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2448363.

Some on the Federal Circuit, too, have similarly understood the *Morse* case in the same vein, characterizing the case as “holding ineligible a claim pre-empting all uses of electromagnetism to print characters at a distance.” *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008)(en banc)(Michel, C.J.), *aff’d sub nom Bilski v. Kappos*, 561 U.S. 593 (2010).

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A different view is taken in a dissent:

The majority ... relies on *O'Reilly v. Morse*[, 56 U.S. (15 How.) 62 (1853),] citing the Court's rejection of Morse's Claim 8 for "the use of the motive power of the electro or galvanic current, which I call electromagnetism, however developed, for making or printing intelligible characters, signs or letters at any distances" The Court explained:

"In fine he claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent. The Court is of the opinion that the claim is too broad, and not warranted by law."

56 U.S. (15 How.) at 113. However, the claims that were directed to the communication system that was described by Morse were held patentable, although no machine, transformation, or manufacture was required. *See Morse's Claim 5* ("The system of signs, consisting of dots and spaces, and horizontal lines, for numerals, letters, words, or sentences, substantially as herein set forth and illustrated, for telegraphic purposes."). I cannot discern how the Court's rejection of Morse's Claim 8 on what would now be Section 112 grounds, or the allowance of his other claims, supports this court's ruling today.

Bilski, 545 F.3d at 983-84 (Newman, J.).

In fact, taking a snapshot view of a case from more than 160 years ago, *in vacuo*, is itself dangerous. In order to fully understand *O'Reilly v. Morse* it is necessary to recognize the *context* of the Antebellum Era in which the case was decided. *See Adam Mossoff, supra*. It is also necessary to go into the record of the case, which puts the opinion in the case in proper context. *Id.*

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As stated by Professor Mossoff:

“Chief Justice Taney’s view of patents as monopoly franchise grants that should be strictly limited in their legal protection * * * does not justify the scholarly and judicial reliance today on [*O’Reilly v.*] *Morse* as a fundamentally correct statement of American patent jurisprudence. It was instead a decision corrupted by policy biases and untrue factual assumptions about the nature of Morse’s patents * * *. In fact, the difficulties courts and scholars have had in converting [*O’Reilly v.*] *Morse* into a definitive legal rule, especially in the patentable subject matter area, may simply be a byproduct of a fundamentally corrupted decision now deemed to be foundational statement for the rule that one cannot patent an ‘abstract idea.’

“[T]he *Morse* myth – that Chief Justice Taney correctly reined in an aggrandizing patentee who was attempting to control electrical telecommunications that went far beyond what he invented – should be officially laid to rest. It is a legally incorrect statement that fails to recognize fundamental differences in patent law doctrine in the Antebellum Era [prior to the establishment of a system of peripheral claiming]. Even worse, it ultimately conceals a politically motivated decision by a Supreme Court Justice who is widely recognized for inappropriate comportment as a governmental official who placed political policy preferences ahead of and in contravention to the law.”

Id. at pp. 71-72 (footnote omitted).

As seen from the work of Professor Mossoff, it is sometimes dangerous for a scholar cabined by a twenty-first century vocabulary and understanding of the modern legal system to accurately understand the meaning of a mid-nineteenth century Supreme Court opinion that having a vintage of more than 165 years. The leading patent scholar-practitioner at the time of *O’Reilly v. Morse* provides a contemporaneous view of the case:

[In *O'Reilly v. Morse*, w]e have seen that it is possible to destroy a claim to a very important and easily understood invention, by separating the principle from its application by the necessary means; and the more striking and comprehensive the discovery of the principle, the greater will be the tendency, perhaps, to fall into this error. Although there are grounds for contending that Morse's specification furnished the materials for saving his eighth claim from this fatal defect, it cannot be denied that it was drawn as to expose it to the force of this objection. What, then, is the proper mode, or one of the proper modes, of avoiding this peril? *The danger of claiming an abstract principle will be avoided by the use of appropriate terms, signifying that the application of the principle is claimed as effected by the means used and described by the patentee, and by all other means which, when applied within the just scope of his conditions, will perform, for the purpose of the application, the like office.* No particular form of words can be suggested capable of general use as a formula. Indeed, formularies are of very little use in this branch of the law; for, to use an expression of Lord Kenyon's, 'there is no magic in words,' as mere words. Words which mean things, and which relate to things, are the important matters of judicial cognizance in determining the meaning and operation of these instruments.

George Ticknor Curtis, *A Treatise on the Law of Patents for Useful Inventions as Enacted and Administered in the United States of America*, § 166, pp. 152-53 (Boston: Little, Brown and Company)(3rd ed. 1867)(emphasis added).*

* The saga of Samuel Morse goes far beyond the Supreme Court case but involved what for patent law involved intensively lobbying by the inventor. Morse was a politically active figure of his era, as manifested, for example, by his successful lobbying to obtain a grant from Congress to further his work. See Steven Lubar, *The Transformation of Antebellum Patent Law*, 32 *Technology and Culture*, 932, 951 n.70 (1991)('Morse hired a lobbyist, spent months lobbying himself, and was successful; the Senate appropriated \$ 30,000 to test his telegraph[.]')(citing Richard John, *A Failure of Vision? Samuel F.B. Morse and the Idea of a Post Office Telegraph, 1844-47*, pp. 28-32 (1988)).

D. The “Abstract” Pencil of the *Rubber-Tip Pencil* Case

Rubber Tip Pencil Co. v. Howard, 87 U.S. (20 Wall.) 498 (1874), has been repeatedly relied upon as basis for the position that an abstract idea is an exception to patent-eligibility under what is today 35 USC § 101.

Rubber-Tip Pencil is a very important case in the area of patent-eligibility precisely because it has been so frequently cited for this proposition. *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)(quoting *Rubber-Tip Pencil*, 87 U.S. (20 Wall.) at 507, for “the longstanding rule that '[a] idea of itself is not patentable.’”); *Parker v. Flook*, 437 U.S. 584, 598-99 (1978) (Stewart, J., joined by Burger, C.J., Rehnquist, J., dissenting)(citing, *inter alia*, *Rubber-Tip Pencil*, 87 U.S. (20 Wall.) at 507, for the proposition that “[a] patent could not issue... on the law of gravity, or the multiplication tables, or the phenomena of magnetism, or the fact that water at sea level boils at 100 degrees centigrade and freezes at zero—even though newly discovered.”); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)(quoting *Rubber-Tip Pencil*, 87 U.S. (20 Wall.) at 507)(“An idea of itself is not patentable[.]”). *See also In re Warmerdam*, 33 F.3d 1354, 1360 (Fed. Cir. 1994)(“As the Supreme Court has made clear, ‘[a]n idea of itself is not patentable; *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498, 507 (1874); taking several abstract ideas and manipulating them together adds nothing to the basic equation.”); *In re Comiskey*, 554 F.3d 967, 978 (Fed. Cir. 2009)(Dyk, J.)(quoting *Rubber-Tip Pencil*, 87 U.S. (20 Wall.) at 507)(“[W]hen an abstract concept has no claimed practical application, it is not patentable. The Supreme Court has held that ‘[a]n idea of itself is not patentable.’”)(original emphasis by the Court).

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“An idea of itself is not patentable” is an out of context quotation, completely divorced from the fact that the issue was *novelty* and not *patent-eligibility*. *Diehr*, 450 U.S. at 185 (quoting *Rubber-Tip Pencil*, 87 U.S. (20 Wall.) at 506). The patentee had an excellent inventive concept but simply failed to *define* his invention in a manner to exclude having the invention read on the prior art: The issue was clearly one of *novelty* and not patent-eligibility.

The question presented was whether the now classic eraser-embedded pencil is *novel*, a point set out in the very first sentence of the opinion: “The question which naturally presents itself for consideration at the outset of this inquiry is, whether the new article of manufacture, claimed as an invention, was patentable as such.” *Rubber-Tip Pencil*, 87 U.S. (20 Wall.) at 506.

In essence, the definition of the invention was stated too broadly to read on subject matter that lacked patentability:

“[T]he patentee is careful to say that 'he does not limit his invention to the precise forms shown, as it may have such or any other convenient for the purpose, so long as it is made so as to encompass the pencil and present an erasive surface upon the sides of the same.' Certainly words could hardly have been chosen to indicate more clearly that a patent was not asked for the external form, and it is very evident that the essential element of the invention as understood by the patentee was the facility provided for attaching the head to the pencil. The prominent idea in the mind of the inventor clearly was the form of the attachment, not of the head.”

Id.

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Thus, the *Rubber-Tip Pencil* case concludes by saying that “[a]n idea of itself is not patentable, but a new device by which it may be made practically useful is. The idea of this patentee was a good one, but his device to give it effect *** was *not new*.” *Rubber-Tip Pencil*, 87 U.S. (20 Wall.) at 507 (emphasis added).



III. MODERN MYTHOLOGY OF A RESEARCH “PREEMPTION”

In the formative years of American patent law of the nineteenth century there never was a concern that broad – or *any* – patents would “preempt” research. This had everything to do with the Story line of case law which established a right to experiment on a patented invention: In other words, the patent right does not extend to block follow-on research on the invention. *See* § III-A, *Story Right To Experiment on a Patented Invention*.

A. *Story Right To Experiment on a Patented Invention*

The Constitutional objective of the patent system is to *encourage* research through patent disclosures. Manifest, the right to conduct follow-on research *on* the patented invention is the heart and soul of the patent system. As stated in the “Promote the Progress” provision of the Constitution:

“Pursuant to its power ‘[t]o promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries,’ U.S. Const., Art. I, § 8, cl. 8, Congress has passed a series of patent laws that grant certain exclusive rights over certain inventions and discoveries as a means of encouraging innovation.”

Bilski, 130 S.Ct. at 3236.

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If patents are to *promote* research it is inherent that the public should be able to experiment on the patented invention without trampling on the commercial rights of the patentee. The right to conduct follow-on research within the scope of a patented invention, to thus experiment *on* a patented invention, stems from the interpretation of the Constitution by legendary Supreme Court Justice Joseph Story.

The “Promote the Progress” Clause of the Constitution governs intellectual property rights for both copyrights and patents. For both, the Clause provides the foundation for exemptions from infringement for fair use or experimental use, respectively, because such exemptions “promote the Progress”.

“[T]he primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is ‘to promote the progress of science and useful arts.’”

Quanta Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617, 626 (2008), quoting *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917).

In the quoted *Motion Picture Patents* case, historical perspective is provided:

“Since *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829)[(Story, J.)], was decided ..., this court has consistently held that the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents, but is ‘to promote the progress of science and the useful arts’ (Constitution, art. 1, § 8),-an object and purpose authoritatively expressed by Mr. Justice Story, in that decision, saying:

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“ ‘While one great object [of our patent laws] was, by holding out a reasonable reward to inventors and giving them an exclusive right to their inventions for a limited period, to stimulate the efforts of genius, the main object was ‘to promote the progress of science and useful arts.’ ”

“Thirty years later this court, returning to the subject, in *Kendall v. Winsor*, 62 U.S. (21 How.) 322 (1858), again pointedly and significantly says:

“‘It is undeniably true, that the limited and temporary monopoly granted to inventors was never designed for their exclusive profit or advantage; the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly.’ ”

“This court has never modified this statement of the relative importance of the public and private interests involved in every grant of a patent, even while declaring that, in the construction of patents and the patent laws, inventors shall be fairly, even liberally, treated. *Grant v. Raymond*, 31 U.S. (6 Pet.) 218 (1832); *Winans v. Denmead*, 56 U.S. (15 How.) 330 (1854); Walker, Patents, § 185.”

Motion Picture Patents, 243 U.S. at 510-11.

Sixteen years before *Pennock v. Dialogue*, the author of that case explained the right to experiment on a patented invention:

“[I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for [scientific] experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”

Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) (Story, J.)(riding circuit) (The text of the opinion speaks of “philosophical experiments” which, in the context of contemporary usage, means “scientific experiments”).

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Whittemore v. Cutter is not an isolated case. Justice Story next explained the right to experiment *on* a patented invention in *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391) (Story, J.). There, Justice Story first emphasizes that commercial use of an invention is patent infringement. “[T]he making of a patented machine to be an offence within the purview of it, must be the making with an intent to use for profit....” *Sawin v. Guild*, 21 F. Cas. at 555.

But, as a caveat, there is no infringement if the use of the invention was “for the mere purpose of [scientific] experiment, or to ascertain the verity and exactness of the specification.” *Id.*

As previously explained:

“*Evans v. Eaton*, [16 U.S. (3 Wheat.) 454 (1818),]...sheds further light on the view that there should be experimenting on a patented invention to make a yet further patented invention – but that the commercial practice of that later patented invention had to give way to the rights of the earlier patentee. Thus, *Evans* recognizes that an infringing improvement invention can be made during the term of an earlier patent, but not practiced commercially free from the senior patent. Citing as authority a contemporaneous English precedent,

Evans states that “[i]f a person has invented an improvement upon an existing patented machine, he is entitled to a patent for his improvement; but he cannot use the original machine, until the patent for it has expired.”

Wegner, *Post-Merck Experimental Use and the “Safe Harbor,”* 15 Fed. Cir. B.J. 1, 7 (2005) (quoting *Evans*, 16 U.S. (3 Wheat.) app. at 17, citing *Ex parte Fox*, 35 Eng. Rep. 26 (1812) (The Lord Chancellor Eldon)). Professor Dreyfuss quotes with approval from Professor William Robinson's leading late nineteenth century patent law treatise:

“[W]here [the patented invention] is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of intellectual character But if the products of the experiment are sold ... the acts of making or of use are violations of the rights of the inventor and infringements of his patent.”

Rochelle Cooper Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 Ariz. L. Rev. 457, 458 (2004) (quoting William C. Robinson, *The Law of Patents for Useful Inventions* § 898 (1890)).

Professor Dreyfuss concludes that “[i]n other words, to early jurists, a clear distinction could be made between using patented material to learn about the patented invention and using patented material for business or for commerce-- between using the patent to satisfy curiosity or using it to turn a profit.”

Id.

With citations again starting with Joseph Story, the Supreme Court in the *Pretty Woman* Case explains the “Promote the Progress” Clause in the copyright context:

“ From the infancy of copyright protection, some opportunity for fair use of copyrighted materials has been thought necessary to fulfill copyright's very purpose, ‘[t]o promote the Progress of Science and useful Arts....’ U.S. Const., Art. I, § 8, cl. 8. For as Justice Story explained, ‘[i]n truth, in literature, in science and in art, there are, and can be, few, if any, things, which in an abstract sense, are strictly new and original throughout. Every book in literature, science and art, borrows, and must necessarily borrow, and use much which was well known and used before.’ *Emerson v. Davies*, 8 F.Cas. 615, 619 (No. 4,436) (CCD Mass.1845).

Similarly, Lord Ellenborough expressed the inherent tension in the need simultaneously to protect copyrighted material and to allow others to build upon it when he wrote, ‘while I shall think myself bound to secure every man in the enjoyment of his copy-right, one must not put manacles upon science.’ *Carey v. Kearsley*, 4 Esp. 168, 170, 170 Eng.Rep. 679, 681 (K.B.1803). In copyright cases brought under the Statute of Anne of 1710, [An Act for the Encouragement of Learning, 8 Anne, ch. 19,] English courts held that in some instances ‘fair abridgements’ would not infringe an author’s rights, see W. Patry, *The Fair Use Privilege in Copyright Law* 6-17 (1985) []; Leval, *Toward a Fair Use Standard*, 103 Harv.L.Rev. 1105 (1990)[], and although the First Congress enacted our initial copyright statute, Act of May 31, 1790, 1 Stat. 124, without any explicit reference to ‘fair use,’ as it later came to be known, the doctrine was recognized by the American courts nonetheless.”

Pretty Woman Case, *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 576-76 (1994)(footnotes deleted). Again in the copyright context in *Eldred*, the “Promote the Progress” clause was explained by reference to patents:

“‘[I]mplicit in the Patent Clause itself’ is the understanding ‘that free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception. Moreover, the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure.’” *Eldred v. Ashcroft*, 537 U.S. 186, 225 (2003)(Stevens, J., dissenting)(quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989)).

A principal author of the 1952 Patent Act, the late Giles Sutherland Rich, stated, without qualification, that “experimental use is not infringement[.]” *In re Kirk*, 376 F.2d 936, 965 n.7 (CCPA 1967)(Rich, J., dissenting)(citing *Chesterfield*

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v. United States, 159 F.Supp. 371 (Ct.Cls. 1958); *Whittemore v. Cutter*, 29 Fed.Cas. 1120 (No. 17,600) (C.C.D. Mass.1813); *Sawin v. Guild*, 21 Fed.Cas. 554 (No. 12,391) (C.C.D.Mass.1813); *Kaz Mfg. Co. v. Chesebrough-Ponds, Inc.*, 317 F.2d 679 (2nd Cir. 1963)). *See also* *Bonsack Machine Co. v. Underwood*, 73 F. 206, 211 (C.C.E.D.N.C. 1896)(“The accused devices *** can be eliminated from consideration [as infringement] for it affirmatively appeared *** that [the accused infringer] built that device only experimentally and that it has neither manufactured it for sale nor sold any.”); *Chesterfield*, 159 F.Supp. at 375)(“[T]he evidence shows that a portion of the [patented] alloy procured by the defendant was used only for testing and for experimental purposes, and there is no evidence that the remainder was used other than experimentally. Experimental use does not infringe.”); *Dugan v. Lear Avia, Inc.*, 55 F.Supp. 223, 229 (S.D.N.Y. 1944), *aff’d*, 156 F.2d 29 (2nd Cir. 1946).

B. Current “Research Preemption” Confusion

The preemption concern permeates *Mayo*:

[U]pholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.

* * *

The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?

* * *

Wegner, *Patent Eligibility*

The Court has repeatedly emphasized *** a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature.

* * *

In *Bilski* the Court pointed out that to allow "petitioners to patent risk hedging would preempt use of this approach in all fields."

* * *

[T]here is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify.

* * *

[The claims] threaten to inhibit the development of more refined treatment recommendations ***.

* * *

The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible[.]

.

* * *

[The patentee] encourages us to draw distinctions among laws of nature based on whether or not they will interfere significantly with innovation in other fields now or in the future.

But the underlying functional concern here is a *relative* one: how much future innovation is foreclosed relative to the contribution of the inventor. A patent upon a narrow law of nature may not inhibit future research as seriously as would a

patent upon Einstein's law of relativity, but the creative value of the discovery is also considerably smaller. And, as we have previously pointed out, even a narrow law of nature (such as the one before us) can inhibit future research.

In any event, our cases have not distinguished among different laws of nature according to whether or not the principles they embody are sufficiently narrow. And this is understandable. Courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature. And so the cases have endorsed a bright-line prohibition against patenting laws of nature, mathematical formulas and the like, which serves as a somewhat more easily administered proxy for the underlying "building-block" concern. [citations omitted]

Mayo (citations omitted)

Mayo was followed most recently in the *Myriad* case, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), and *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014). In *Myriad* the Court stated that:

We have “long held that [35 USC § 101] contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable.” *Mayo*, 132 S.Ct. at 1293[]. Rather, “ ‘they are the basic tools of scientific and technological work’ ” that lie beyond the domain of patent protection. *Id.*, 132 S.Ct. at 1293. As the Court has explained, without this exception, there would be considerable danger that the grant of patents would “tie up” the use of such tools and thereby “inhibit future innovation premised upon them.” *Id.*, at —, 132 S.Ct., at 1301. This would be at odds with the very point of patents, which exist to promote creation. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)(Products of nature are not created, and “ ‘manifestations ... of nature [are] free to all men and reserved exclusively to none’ ”).

Myriad, 133 S.Ct. at 2116. Even more recently in *Alice* the Court set forth its understanding of the basis for “preemption” under Section 101:

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We have described the concern that drives this exclusionary principle [under 35 USC § 101] as one of pre-emption. See, *e.g.*, *Bilski* [v. *Kappos*, 561 U.S. 593, 611-12 (2010)] (upholding the patent "would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea"). Laws of nature, natural phenomena, and abstract ideas are " ' the basic tools of scientific and technological work." ' " *Myriad, Association for Molecular Pathology v. Myriad Genetics, Inc.*, [133 S. Ct. 2107, ____ (2013)]. "[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it," thereby thwarting the primary object of the patent laws. *Mayo* [*Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)]; see U. S. Const., Art. I, §8, cl. 8 (Congress "shall have Power . . . To promote the Progress of Science and useful Arts"). We have "repeatedly emphasized this . . . concern that patent law not inhibit further discovery by improperly tying up the future use of " these building blocks of human ingenuity. *Mayo, supra*, at ____ (slip op., at 16) (citing *Morse, supra*, at 113).

* * *

[I]n applying the §101 exception, we must distinguish between patents that claim the "'buildin[g] block[s]" of human ingenuity and those that integrate the building blocks into something more, *Mayo*, 566 U. S. at ____ (slip op., at 20), thereby "transform[ing]" them into a patent-eligible invention, *id.*, at ____ (slip op., at 3). The former "would risk disproportionately tying up the use of the underlying" ideas, *id.*, at ____ (slip op., at 4), and are therefore ineligible for patent protection. The latter pose no comparable risk of pre-emption, and therefore remain eligible for the monopoly granted under our patent laws.

Alice v. CLS Bank, 134 S. Ct. at 2354. Earlier, Circuit Judge Linn had chronicled the Supreme Court focus on "preemption":

"Several [Supreme Court] decisions have looked to the notion of 'preemption' to further elucidate the 'abstract idea' exception [to Section 101 patent-eligibility]. In *Bilski*, the Supreme Court explained that '[a]llowing petitioners to patent risk hedging **would preempt use of this approach in all fields**...' 130 S.Ct. 3231. Previously, in *O'Reilly v. Morse*, 56 U.S. 62 (1853), the Supreme Court held that a claim to electromagnetism was not eligible for patent protection because the

patentee ‘claim[ed] *the exclusive right to every improvement....*’ Id. at 112-13 . The Morse Court reasoned that the claim would effectively ‘*shut[] the door against inventions of other persons . . . in the properties and powers of electro-magnetism*’... Id. at 113 (emphasis added). Again, in *Gottschalk v. Benson*, 409 U.S. 63 (1972), the Supreme Court emphasized the concept of ‘pre-emption,’ holding that a claim directed to a mathematical formula with ‘no substantial practical application except in connection with a digital computer’ was directed to an unpatentable abstract idea because ‘*the patent would wholly pre-empt the mathematical formula...*’ Id. at 71-72. In *Parker v. Flook*, 437 U.S. 584 (1978), the Court again emphasized *the importance of claims not ‘preempting’ the ‘basic tools of scientific and technological work...*’ Id. at 589.

“In contrast to *Morse*, *Benson*, and *Flook*—where the claims were found to ‘pre-empt’ an ‘idea’ or algorithm—in *Diehr*, the Supreme Court held that the claims at issue ... did not ‘*pre-empt the use of th[e] equation.*’ *Diehr*, 450 U.S. at 187. ...

“Our Constitution gave Congress the power to establish a patent system ‘[t]o promote the Progress of Science and useful Arts’ U.S. Const. art. I, § 8, cl. 8. *The patent system is thus intended to foster, not foreclose, innovation.* See *id.*

...[N]o one is entitled to claim an exclusive right to a fundamental truth or disembodied concept that *would foreclose every future innovation in that art.* See *Morse*, 56 U.S. at 112-13. As the Supreme Court has ‘repeatedly emphasized . . . *patent law [must] not inhibit further discovery by improperly tying up the future use of laws of nature.*’ *Prometheus*, 132 S. Ct. at 1301. ‘[T]here is a danger that grant of patents that tie up [laws of nature, physical phenomena, and abstract ideas] will *inhibit future innovation* premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to ‘apply the natural law,’ or otherwise forecloses more future invention than the underlying discovery could reasonably justify.’ Id. (emphasis added)... Thus, *the essential concern is not preemption, per se, but the extent to which preemption results in the foreclosure of innovation.*

Claims that are directed to no more than a fundamental truth and ***foreclose, rather than foster, future innovation*** are not directed to patent eligible subject matter under § 101. ***No one can claim the exclusive right to all future inventions.*** *Morse*, 56 U.S. at 112-13; *Benson*, 409 U.S. at 68.

CLS Bank Int'l v. Alice Corp., 685 F.3d 1341, 1349-51 (Fed. Cir. 2012)(emphasis added), *vacated pet'n reh'g en bnc granted*, 484 Fed.Appx. 559 (Fed.Cir.2012), subsequent opinion, 717 F.3d 1269 (Fed. Cir., 2013)(per curiam)(en banc), *aff'd*, *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014).

C. *Deuterium* Ghost at the Federal Circuit

The Federal Circuit was created to establish a uniform body of patent case law. In the area of whether there is a right to “experiment on” a patented invention, an aberrant line of case law has persisted for more than twenty-five years stemming from the notorious *Deuterium* case that denied the existence of a right to experiment on a patented invention by “question[ing] whether any infringing use can be de minimis. *Deuterium Corp. v. United States*, 19 Cl.Ct. 624 (Cl.Ct.1990)(Rader, J.).

The Federal Circuit to this day is influenced by *Deuterium*, a bold departure from precedent grounded on a unique theory of *de minimis* infringement that was decided by a fresh jurist in his first important patent case who had never practiced law of any kind that was handed down during the jurist’s successful candidacy for a position on the Federal Circuit.

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The ghost of *Deuterium* lives on as foundation for an aberrant line of case law denying a right to “experiment on” a patented invention. *Deuterium* took the unique approach to the experimental use right that questioned “whether any infringing use can be de minimis. Damages for an extremely small infringing use may be de minimis, but infringement is not a question of degree. Damages for an extremely small infringing use may be de minimis, but infringement is not a question of degree.” *Deuterium*, 19 Cl.Ct. at 631 (Cl.Ct.1990)(Rader, J.), followed by *Embrex v. Service Eng'g Corp.*, 216 F.3d 1343 (Fed.Cir.2000) (Rader, J., concurring).

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Another member of the Federal Circuit embraced the same line of thinking. *See Madey v. Duke Univ.*, 307 F.3d 1351 (Fed.Cir.2002)(Gajarsa, J.)(dicta concerning denial of an experimental use right while correctly denying the right to experiment *with* a patented laboratory tool for its intended purpose as a laboratory tool). *See, generally, Wegner, Post-Merck Experimental Use and the “Safe Harbor,”* 15 Fed. Cir. B.J. 1 (2005).

Factually, neither *Deuterium* nor *Madey* has anything to do with an experimentation “on” a patented invention to see how the invention operates or to improve the invention. In both cases, there was experimentation “with” the patented invention. In *Deuterium*, the experimentation “with” the patented invention was to confirm that government contract specification were met and not to design around or otherwise experiment “on” the patented invention. In *Madey*, a patented laboratory tool was used to conduct research and not to study the laboratory tool itself. The use of the patented invention would be more akin to the situation where a microscope is patented and the accused infringement is the use of the microscope to study a subject – an experimentation *with* the microscope, as opposed to studying the microscope itself, to, for example, improve the microscope or understand its operation, an experimentation *on* the microscope.

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Despite the irrelevancy of the holdings in both *Deuterium* and *Madey* to the issue of experimentation *on* a patented invention, where the precise factual situation of an experimentation *on* a patented invention was raised in *Integra Life Sciences I*, the accused infringer *waived* this argument, manifesting how strongly the *Deuterium* line of case law had taken hold at the Federal Circuit. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *rev'd sub nom Merck KGaA v Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

In *Integra Life Sciences I*, despite the fact that the accused infringer waived the right to rely upon the experimental use doctrine, a dissenting member of the panel *sua sponte* raised the issue. To this point, the author of the *Deuterium* case answered:

In her dissent, Judge Newman takes this opportunity to restate her dissatisfaction with this court's decision in *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed.Cir.2002). However, the common law experimental use exception is not before the court in the instant case. *** On appeal, Merck does not contend that the common law research exemption should apply to any of the infringing activities evaluated by the jury. *** Moreover, during oral arguments, counsel for Merck expressly stated that the common law research exemption is not relevant to its appeal. Judge Newman's dissent, however, does not mention that the Patent Act does not include the word "experimental," let alone an experimental use exemption from infringement. See 35 U.S.C. § 271 (2000). Nor does Judge Newman's dissent note that the judge-made doctrine is rooted in the notions of de minimis infringement better addressed by limited damages. *Embrex v. Service Eng'g Corp.*, 216 F.3d 1343 (Fed.Cir.2000) (Rader, J., concurring); see also *Deuterium Corp. v. United States*, 19 Cl.Ct. 624, 631 (Cl.Ct.1990) ("This court questions whether any infringing use can be de minimis. Damages for an extremely small infringing use may be de minimis, but infringement is not a question of degree.").

Integra Lifesciences I, 331 F.3d at 863 n.2.

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One relatively new jurist has swallowed the *Deuterium* Kool-Aid but with citation to Supreme Court precedent: “The Supreme Court has made clear that the principle of preemption is the basis for the judicial exceptions to patentability. *Alice* [*Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014)] (“We have described the concern that drives this exclusionary principal as one of pre-emption”). For this reason, questions on preemption are inherent in and resolved by the § 101 analysis. The concern is that “patent law not inhibit further discovery by improperly tying up the future use of these building blocks of human ingenuity.” *Id.* (internal quotations omitted). In other words, patent claims should not prevent the use of the basic building blocks of technology—abstract ideas, naturally occurring phenomena, and natural laws.” *Ariosa*, ___ F.3d at ___ (Reyna, J.)



IV. PATENT-ELIGIBILITY OF THE *CLAIMED* INVENTION

A. The Invention “As a Whole”

It is fundamental that the *claimed invention* including all of its elements should be evaluated and not dissected element by element. This is explained in the *Adams Battery* case:

“While the claims of a patent limit the invention, and specifications cannot be utilized to expand the patent monopoly, *Burns v. Meyer*, 100 U.S. 671, 672 (1880); *McCarty v. Lehigh Valley R. Co.*, 160 U.S. 110, 116 (1895), it is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention, *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 547 (1871); *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 312 U.S. 654 (1940); *Schering Corp. v. Gilbert*, 153 F.2d 428 (2nd Cir. 1946).”

Adams Battery case, *United States v. Adams*, 383 U.S. at 48-49.

Looking to the claimed invention *as a whole* including all its features is axiomatic from the case law in the field of chemistry and biotechnology. *See In re Dillon*, 919 F.2d 688, 701 (Fed. Cir. 1990)(en banc)(Newman, J., joined by Cowen, Mayer, JJ., dissenting) (“[P]ertinent considerations in determination of whether a prima facie case [of obviousness] is made include the closeness of the prior art subject matter to the field of the invention, the motivation or suggestion in the prior art to combine the reference teachings, the problem that the inventor was trying to solve, the nature of the inventor's improvement as compared with the prior art, and a variety of other criteria as may arise in a particular case; *all with respect to the invention as a whole*, and decided from the viewpoint of a person of ordinary skill in the field of the invention.”)(emphasis added). Thus, determination

of obviousness [is made] by comparing the structures and properties taught in the prior art with those disclosed by the applicant, and bringing judgment to bear on ‘the subject matter as a whole.’” *Id.*, 919 F.2d at 705 (quoting *In re de Montmollin*, 344 F.2d 976, 979 (CCPA 1965))

It is axiomatic that the patentability of a *claim* to a *combination* of elements must be judged in terms of the *claimed combination* including all of its elements and – particularly – the determination whether there is *motivation* to combine the several elements in the manner *stated in the claim*.

It has been hornbook patent law since the nineteenth century that a combination invention must be viewed *as claimed* and that by including a specific element in the claim, that specific element is a material part of the combination that cannot be ignored. Whether that element, *in vacuo*, is “conventional”, the overriding issue is whether *the invention* – the claimed combination – is or is not obvious. In the context of patent infringement it has been well settled that a combination claim must be viewed as that – an invention to the *combination* – and not from the standpoint of any of the component elements, alone. *Prouty v. Draper*, 41 U.S. (16 Pet.) 335 (1842); *Vance v. Campbell*, 66 U.S. (1 Black) 427, 429 (1861); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 337 (1879); *White v. Dunbar*, 119 U.S. 47 (1886). As explained in these cases in the context of infringement:

Where “[t]he patent is for a combination ... [that] is the thing patented. The use of any two of these parts only, or of two combined with a third, which is

substantially different, in form, or in the manner of its arrangement and connection with the others, is, therefore, not the thing patented.” *Prouty v. Draper*, 41 U.S. (16 Pet.) at 341.

“The combination is an entirety; if one of the elements is given up, the thing claimed disappears.” *Vance v. Campbell*, 66 U.S. (1 Black) at 429 (1861).

“[T]he courts of this country cannot always indulge the same latitude which is exercised by English judges in determining what parts of a machine are or are not material. Our law requires the patentee to specify particularly what he claims to be new, and if he claims a combination of certain elements or parts, we cannot declare that any one of these elements is immaterial. The patentee makes them all material by the restricted form of his claim.” *Water-Meter v. Desper*, 101 U.S. (11 Otto) at 337.

“The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.” *White v. Dunbar*, 119 U.S. at 52.

As explained by the Court in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), in the case of a claim to a combination patent, the issue is “to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead,

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there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness’).” As explained in *Kahn*:

Most inventions arise from a combination of old elements and each element may often be found in the prior art. [*In re Rouffet*, 149 F.3d 1350, 1357 (Fed.Cir. 1998)]. However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole. *Id.* at 1355, 1357. Rather, to establish a prima facie case of obviousness based on a combination of elements disclosed in the prior art, the Board must articulate the basis on which it concludes that it would have been obvious to make the claimed invention. *Id.* In practice, this requires that the Board ‘explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.’ *Id.* at 1357-59.

In re Kahn, 441 F.3d 977, 984 (Fed. Cir. 2006)(Linn, J.).

The importance of looking to the *claim* as the definition of the invention was stressed in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005)(en banc). As explained by Circuit Judge Bryson:

“Because the patentee is required to ‘define precisely what his invention is,’ the Court explained, it is ‘unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.’” *White v. Dunbar*, 119 U.S. 47, 52(1886); *see also Cont’l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419 (1908) (‘the claims measure the invention’); *McCarty v. Lehigh Valley R.R. Co.*, 160 U.S. 110, 116 (1895) (‘if we once begin to include elements not mentioned in the claim, in order to limit such claim ..., we should never know where to stop’); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) (‘the claims made in the patent are the sole measure of the grant’).”

Phillips v. AWH, 415 F.3d at 1312.

B. *Mayo* Dissection of the Claim into its Component Parts

Claimed subject matter to a combination invention is “inventive” – or nonobvious under the 1952 Patent Act – where the *combination* is nonobvious. Thus, even though each of the components of the claimed invention may lack novelty, a critical question of inventiveness or nonobviousness of the claim to the combination is whether or not there is *motivation* to create the claimed combination.

Mayo conflicts with precedent by dissecting a combination claim to consider whether each of the components, itself, is inventive or nonobvious, and not whether the *combination* of elements is or is not inventive or nonobvious. The dissection of elements of the claimed invention in *Mayo* is instructive of the flawed Supreme Court reasoning:

What else is there in the claims before us [beyond the natural phenomenon]? The process that each claim recites tells doctors interested in the subject about the correlations that the researchers discovered. In doing so, it recites an "administering" step, a "determining" step, and a "wherein" step. These additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim.

[T]o consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. See *Diehr, supra*, at 188 ("[A] new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made"). Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.

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The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; *any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.* For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

* * *

[T]he claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law. *These instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field.* And since they are steps that must be taken in order to apply the laws in question, the effect is simply to tell doctors to apply the law somehow when treating their patients. ***

Mayo, __ U.S. at __ (emphasis supplied; citations omitted).



V. PATENT ELIGIBILITY AND PATENTABILITY CONFLATION

A. Patent-Eligible Subject Matter over the Past 200 Years

For several hundred years first in England and then in America there had been a common understanding that tangible subject matter of all kinds was patent *eligible* and also *patentable* if it met the patentability tests of novelty and – as from the mid-nineteenth century – and possessed “invention” – or an “inventive” feature, as from a body of case law that developed through case law beginning in the mid-nineteenth century that was codified in the 1952 Patent Act as 35 USC § 103. This common understanding was shattered by Supreme Court decisions in *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Parker v. Flook*, 437 U.S. 584 (1978), but the pendulum swung back to the historical common understanding with *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); and *Diamond v. Diehr*, 450 U.S. 175 (1981). Thirty years after *Benson* uncertainty returned with *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Parker v. Flook*, 437 U.S. 584 (1978).

The history of patent eligibility is traced by the late Giles Sutherland Rich in his tour de force exposition of the law in *In re Bergy*, 596 F.2d 952 (CCPA 1979)(Rich, J.), *aff'd as to Chakrabarty sub nom Diamond v. Chakrabarty*, 447 U.S. 303 (1980). (The *Bergy* opinion was a joint opinion for both the *Bergy* and *Chakrabarty* cases; following grant of *certiorari* in both cases, Respondent Bergy mooted his appeal by cancelling the sole claim in controversy, whereupon the Supreme Court proceedings continued as to *Chakrabarty* while the court dismissed the appeal as to *Bergy*). As explained by Judge Rich in *Bergy*:

“Anatomy of the Patent Statute

“*** [W]e find in *Flook* an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated, namely, those pertaining to the *categories* of inventions in § 101 which *may* be patentable and to the *conditions* for patentability demanded by the statute for inventions within the statutory categories, particularly the nonobviousness condition of § 103. The confusion creeps in through such phrases as ‘eligible for patent protection,’ ‘patentable process,’ ‘new and useful,’ ‘inventive application,’ ‘inventive concept,’ and ‘patentable invention.’ The last-mentioned term is perhaps one of the most difficult to deal with unless it is used *exclusively* with reference to an invention which complies with *every* condition of the patent statutes so that a valid patent may be issued on it.

“The problem of accurate, unambiguous expression is exacerbated by the fact that prior to the Patent Act of 1952 the words ‘invention,’ ‘inventive,’ and ‘invent’ had distinct legal implications related to the concept of patentability which they have not had for the past quarter century. Prior to 1952, and for sometime thereafter, they were used by courts as imputing *patentability*. Statements in the older cases must be handled with care lest the terms used in their reasoning clash with the reformed terminology of the present statute; lack of meticulous care may lead to distorted legal conclusions. “

{“Invention” Changed to Nonobviousness in the 1952 Patent Act}

“The transition made in 1952 was with respect to the old term ‘invention,’ imputing *patentability*, which term was replaced by a new statutory provision, § 103, requiring *nonobviousness*, as is well explained and approved in *Graham v. John Deere Co.*, supra n. 2. Part IV of that opinion, entitled ‘The 1952 Act,’ quotes the key sections of the statute upon which patentability depends. *Graham* states that there are three explicit conditions, novelty, utility, and nonobviousness, which is true, but there is a fourth requirement, which alone, is involved here. This was also the sole requirement involved in *Flook*.

“The Revised Statutes of 1874, which contained the primary patent statutes revised and codified in 1952, lumped most of the conditions for patentability in a single section, § 4886, as did all of the prior statutes back to the first one of 1790.

The 1952 Act divided that statute up into its logical components and *added* the nonobviousness requirement, which until then had been imposed only by court decisions. This attempt at a clearcut statement to replace what had been a hodgepodge of separate enactments resulted in a new and official Title 35 in the United States Code with three main divisions. Part I pertains to the establishment and organization of the PTO. Part II, here involved, covers patentability of inventions and the grant of patents. Part III relates to issued patents and the protection of the rights conferred by them.

“All of the statutory law relevant to the present cases is found in four of the five sections in Chapter 10, the first chapter of Part II:

“Sec. 100 Definitions

“Sec. 101 Inventions patentable if they qualify

“Sec. 102 Conditions for patentability; novelty and loss of right to patent

“Sec. 103 Conditions for patentability; non-obvious subject matter

“More strictly speaking, these cases involve only § 101, as did *Flook*. Achieving the ultimate goal of a patent under those statutory provisions involves, to use an analogy, having the separate keys to open in succession the three doors of sections 101, 102, and 103, the last two guarding the public interest by assuring that patents are not granted which would take from the public that which it already enjoys (matters already within its knowledge whether in actual use or not) or *potentially* enjoys by reason of obviousness from knowledge which it already has.

“Inventors of patentable inventions, as a class, are those who bridge the chasm between the known and the obvious on the one side and that which promotes progress in useful arts or technology on the other.

{“First Door”, Section 101 Patent-Eligibility }

“The first door which must be opened on the difficult path to patentability is § 101 (augmented by the § 100 definitions), quoted *supra* p. 956. The person approaching that door is *an inventor*, whether his invention is patentable or not. There is always an inventor; being an inventor might be regarded as a preliminary legal requirement, for if he has not invented something, if he comes with something he knows was invented by someone else, he has no right even to

approach the door. Thus, section 101 begins with the words ‘Whoever invents or discovers,’ and since 1790 the patent statutes have always said substantially that. Being an inventor or having an invention, however, is no guarantee of opening even the first door. What *kind* of an invention or discovery is it? In dealing with the question of kind, as distinguished from the qualitative conditions which make the invention patentable, § 101 is broad and general; its language is: ‘any * * * process, machine, manufacture, or composition of matter, or any * * * improvement thereof.’ Section 100(b) further expands ‘process’ to include ‘art or method, and * * * a new use of a known process, machine, manufacture, composition of matter, or material.’ If the invention, as the inventor defines it in his claims (pursuant to § 112, second paragraph), falls into any one of the named categories, he is allowed to pass through to the second door, which is § 102; ‘novelty and loss of right to patent’ is the sign on it. Notwithstanding the words ‘new and useful’ in § 101, the invention is not examined under that statute for novelty because that is not the statutory scheme of things or the long-established administrative practice.

“Section 101 *states* three requirements: novelty, utility, and statutory subject matter. The understanding that these three requirements are *separate and distinct* is long-standing and has been universally accepted. The text writers are all in accord and treat these requirements under separate chapters and headings. *See, e. g., Curtis's Law of Patents*, Chapters I and II (1873); 1 *Robinson on Patents* §§ 69-70 at 105-109 (1890); 1 *Rogers on Patents* (1914); *Revise & Caesar, Patentability and Validity*, Chapters II, III, IV (1936); *Deller's Walker on Patents*, Chapters II, IV, V (1964). Thus, the questions of whether a particular invention is *novel* or *useful* are questions wholly apart from whether the invention falls into a category of *statutory subject matter*. Of the three requirements *stated* in § 101, only two, utility and statutory subject matter, are *applied* under § 101. As we shall show, in 1952 Congress voiced its intent to consider the novelty of an invention under § 102 where it is first made clear what the statute means by ‘new’, notwithstanding the fact that this requirement is first *named* in § 101.

“The PTO, in administering the patent laws, has, for the most part, consistently applied § 102 in making rejections for lack of novelty. To provide the option of making such a rejection under either § 101 or § 102 is confusing and therefore bad law. Our research has disclosed only two instances in which rejections for lack of novelty were made by the PTO under § 101, *In re Bergstrom*,

427 F.2d 1394 (CCPA 1970); *In re Seaborg*, 328 F.2d 996 (CCPA 1964). In *In re Bergstrom* we in effect treated the rejection as if it had been made under § 102, observing in the process that ‘The word ‘new’ in § 101 is defined and is to be construed in accordance with the provisions of § 102.’ 427 F.2d at 1401.

* * *

{“Second Door”, Section 102 Novelty}

“The second door ... is § 102 pursuant to which the inventor's claims are examined for novelty, requiring, for the first time in the examination process, comparison with the prior art which, up to this point, has therefore been irrelevant.

“Section 102 also contains other conditions under the heading ‘loss of right’ which need not be considered here. An *invention* may be in a statutory category and not patentable for want of *novelty*, or it may be novel and still not be patentable because it must meet yet another condition existing in the law since 1850 when *Hotchkiss v. Greenwood*, 11 How. 248, was decided. This condition developed in the ensuing century into the ‘*requirement for invention*.’ See *Graham v. John Deere Co.*, *supra*.

{“Third Door”, Section 103 Nonobviousness, Codifying “Invention”}

“The third door, under the 1952 Act, is § 103 which was enacted *to take the place of the requirement for ‘invention.’* ***

“Section 103, for the first time in our statute, provides a condition which exists in the law and has existed for more than 100 years, but only by reason of decisions of the courts. An *invention* which has been made, and which is new in the sense that the *same* thing has not been made or known before, may still not be patentable if the difference between the new thing and what was known before is not considered sufficiently great to warrant a patent. That has been expressed in a large variety of ways in decisions of the courts and in writings. Section 103 states this requirement in the title ‘Conditions for patentability; non-obvious subject matter’. It refers to the difference between the subject matter sought to be patented *and the prior art*, meaning what was known before as described in section 102. If this difference is

such that *the subject matter as a whole* would have been obvious at the time the invention was made to a person ordinarily skilled in the art, then the subject matter cannot be patented. Insertions and emphasis ours.

{ The Three Keys }

“If the inventor holds the three different keys to the three doors, his *invention* (here assumed to be ‘useful’) qualifies for a patent, otherwise not; but he, as *inventor*, must meet still other statutory requirements in the preparation and prosecution of his patent application. We need not here consider the latter because appellants have not been faulted by the PTO in their paperwork or behavior. The point not to be forgotten is that being an *inventor* and having made an *invention* is not changed by the fact that one or more or all of the conditions for *patentability* cannot be met. Year in and year out this court turns away the majority of the inventors who appeal here because their inventions do not qualify for patents. They remain inventions nevertheless. It is time to settle the point that the terms *invent*, *inventor*, *inventive*, and the like are unrelated to deciding whether the statutory requirements for patentability under the 1952 Act have been met. There is always *an invention*; the issues is its patentability. Terms like ‘inventive application’ and ‘inventive concept’ no longer have any useful place in deciding questions under the 1952 Act, notwithstanding their universal use in cases from the last century and the first half of this one. ***

Bergy (Headlines in bracing are added for clarity; footnotes omitted).

B. “Inventive” Subject Matter Prior to the 1952 Patent Act

In the context of the 1952 Patent Act, the Supreme Court has equated “inventive concept”, “inventive” and “inventiveness” with statutory nonobviousness. *See, e.g., Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 632 (2008)(discussing “the essential, or inventive, feature of the [] patents”); *id.* at 635 (“the inventive part of the patent”); *Ill. Tool Works Inc. v. Independent*

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Ink, Inc., 547 U.S. 28, 41 (2006) (“elements essential to the inventive character of the patent”); *Eldred v. Ashcroft*, 537 U.S. 186, 242 (2003) (Stevens, J., dissenting) (“the products of inventive ... genius”); *Traffix Devices, Inc. v. Marketing Displays, Inc.*, 532 U.S. 23, 28 (2001) (quoting *Vornado Air Circulation Systems, Inc. v. Duracraft Corp.*, 58 F.3d 1498, 1500 (10th Cir. 1995) (“product configuration is a significant inventive component of an invention”)); cf. *Quanta*, 553 U.S. at 634 (“common and noninventive”); *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 277 (1976) (invention unpatentable because “[t]he only claimed *inventive feature*” falls short of the test for nonobviousness under 35 USC § 103) (emphasis added).

The several Circuit Courts of Appeal have also referred to an “inventive concept” in lieu of the statutory term nonobviousness. The Third Circuit spoke of patentability in terms of subject matter being “inventive”, and as having an “inventive concept”: “Since *Miller v. Eagle*[, 151 U.S. 186 (1894)], courts have repeatedly ruled that an inventor's separate applications embodying the same *inventive concept* afford proper bases for the issuance of separate patents at different times only if one of them also embodies an additional *inventive concept* not present in the other. In other words, *the difference between the claims of the two applications must itself be inventive.*” *Wahl v. Rexnord, Inc.*, 624 F.2d 1169 1178 (3rd Cir. 1980) (quoting *Pierce v. Allen B. DuMont Laboratories, Inc.*, 297 F.2d 323, 327 (3d Cir. 1961)) (emphasis added). See also *Forbro Design Corp. v. Raytheon Co.*, 532 F.2d 758, 765 (1st Cir. 1976) (“Dr. Kupferberg had deposed that the *inventive concept* was contained in the first few paragraphs of the patent[.]”) (emphasis added); *Olympic Fastening Systems, Inc. v. Textron, Inc.*, 504

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F.2d 609, 616 (6th Cir.1974)(The witness Ketchum testified ... that the extent to which the [feature] is not a part of the *inventive concept* of the Gapp patent.”)(emphasis added); *Groen v. General Foods Corp.*, 402 F.2d 708, 711 (9th Cir. 1968)(“[A]ppellants rely principally upon the alleged *inventive concept* involved in the combination of steps set forth in the claim.”); *Ellipse Corp. v. Ford Motor Co.*, 452 F.2d 163, 167 (7th Cir. 1971)(“This purported [limitation] is *the inventive concept* of the pump and distinguishes it from the prior art.”)(emphasis added); *McCullough Tool Co. v. Well Surveys, Inc.*, 343 F.2d 381, 397 (10th Cir. 1965)(“The asserted *inventive concept* of the patent in suit is an alleged new combination of elements having a new mode of operation[.]”)(emphasis added).

To be sure, there is plenty of rhetoric in Supreme Court cases referring to a long-standing requirement for “invention” in the older case law. Taken in context of decisions prior to the 1952 Patent Act, the requirement for “invention” referred to the requirement for a *patentable difference* versus the prior art, what today under the statute is nonobviousness under the 1952 Patent Act:

A prime example is *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130-31 (1948). It is crystal clear that *Funk v. Kalo* was focused on the lack of a *patentable difference* for the claimed invention versus the prior art and not on patent-eligibility under what is today 35 USC § 101. See Jeffrey A. Lefstin, *Inventive Application: A History* (2014), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2398696; Lefstin & Menell, *amicus* brief in *Alice Corporation Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014), http://www.americanbar.org/content/dam/aba/publications/supreme_court_pre

[view/briefs-v3/13-298_resp_amcu_profs-psm-jal.authcheckdam.pdf](#). See also Shine Tu, *Funk Brothers – an Exercise in Obviousness*, 80 UMKC L. Rev. 637, 637-38 (2012)).

In the *Bergy* case the late Giles Sutherland Rich explained the same point in the context of the Supreme Court *Flook* opinion:

“[W]e find in *Flook* an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated, namely, those pertaining to the *categories* of inventions in § 101 which *may* be patentable and to the *conditions* for patentability demanded by the statute for inventions within the statutory categories, particularly the nonobviousness condition of § 103.

The confusion creeps in through such phrases as ‘eligible for patent protection,’ ‘patentable process,’ ‘new and useful,’ ‘inventive application,’ ‘inventive concept,’ and ‘patentable invention.’ The last mentioned term is perhaps one of the most difficult to deal with unless it is used *exclusively* with reference to an invention which complies with *every* condition of the patent statutes so that a valid patent may be issued on it.”

In re Bergy, 596 F.2d 952, 959 (CCPA 1979), *aff’d sub nom Diamond v. Chakrabarty*, 447 U.S. 303 (1980).



VI. THE *GRAHAM* STATUTORY NONOBVIOUSNESS INQUIRY

While it may often be the case that a generic description of software in a combination claim may not add a nonobvious feature, this is not necessarily the case. But, under *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), a generic recitation of a software element may be disregarded. To “apply it” (the software) adds no inventive step (per *Mayo*).

A. The Fact-Intensive Four Factor *Graham* Test

A determination of “obviousness depends on several underlying factual inquiries. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); see also *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811 (1986) (holding that Rule 52(a) requires that the district court's subsidiary factual determinations should be reviewed for clear error); cf. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 336 U.S. 271, 275 (1949) (holding that validity, while ultimately a question of law, is founded on factual determinations that are entitled to deference). ‘Under [section] 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.’ *Graham*, 383 U.S. at 17.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1333 (Fed. Cir. 2005)(en banc)(Mayer, J., joined by Newman, J., dissenting).

“It is, of course, beyond peradventure that the trier of fact must answer the *Graham* inquiries relating to ‘(1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary

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skill in the art at the time when the invention was made; and (4) objective evidence of nonobviousness.” *In re Lockwood*, 50 F.3d 966, 970 n.4 (Fed. Cir. 1995)(quoting *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 989 (Fed.Cir.1988))

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The “apply it” test simply bypasses the full consideration of the four factors to determine nonobviousness established in *Graham v. John Deere Co.*, 383 U.S. 1 (1966): “It is, of course, beyond peradventure that the trier of fact must answer the *Graham* inquiries relating to ‘(1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time when the invention was made; and (4) objective evidence of nonobviousness.” *In re Lockwood*, 50 F.3d 966, 970 n.4 (Fed. Cir.

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1995)(quoting *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 989 (Fed.Cir.1988)).

With regard to motivation, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), is relevant. In this case of a claim to a combination patent, the issue is “to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)(‘[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness’).” As explained in *Kahn*:

Most inventions arise from a combination of old elements and each element may often be found in the prior art. [*In re Rouffet*, 149 F.3d 1350, 1357 (Fed.Cir. 1998)]. However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole. *Id.* at 1355, 1357. Rather, to establish a prima facie case of obviousness based on a combination of elements disclosed in the prior art, the Board must articulate the basis on which it concludes that it would have been obvious to make the claimed invention. *Id.* In practice, this requires that the Board ‘explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.’ *Id.* at 1357-59.

In re Kahn, 441 F.3d 977, 984 (Fed. Cir. 2006)(Linn, J.).

With regard to the level of skill in the art, *Graham v. Deere* is followed, for example, in *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co*, 396 U.S. 57 (1969); *Dann v. Johnston*, 425 U.S. 219 (1976); *Sakraida v. Ag Pro, Inc*, 425 U.S. 273 (1976), where a *mandatory* determination is required of three factors including

determination of the level of ordinary skill in the art. *Anderson's Black- Rock*, 396 U.S. at 61(quoted *Graham*, 383 U.S. at 17)(“Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.”); *Dann v. Johnston*, 425 U.S. at 226 (citing *Graham*, 383 U.S. at 17, for the proposition that “the level of ordinary skill in the pertinent art” is a “central factor[] relevant to any inquiry into obviousness[.]”); *Sakraida*, 425 U.S. at 280(“[R]esolution of the obviousness issue necessarily entails several basic factual inquiries, *Graham v. John Deere Co.*, [383 U.S. 1, 17 (1966)]. Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.” Ibid.”)

Even though in each of these the conclusion was one of obviousness, each case followed the “three factors” methodology. “We admonished that 'strict observance' of those requirements is necessary.” *Anderson's-Black Rock, Inc. v. Pavement Salvage Co*, 396 U.S. 57, 61 (1969)(quoting *Graham v. John Deere Co.*, 383 U.S. at 18).

Beginning with *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); and *Diamond v. Diehr*, 450 U.S. 175 (1981), and continuing for thirty years, the Supreme Court had kept an open door to patent-eligibility of new technology. Then, in 1980, the Court has reopened the door to reconsider its patent-eligibility stance in a series of negative rulings in *Bilski v. Kappos*, 561 U.S. 593 (2010); *Mayo Collaborative*

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Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012), the *Myriad* case, *Association for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013), and *Alice Corporation Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014).

At the beginning of 2015 it was widely predicted that legislation would be introduced in Congress that would provide a legislative solution to the *Alice* challenge. There is absolutely no certainty that legislation can or will be enacted: It is far simpler to kill pending legislation than to obtain passage; given powerful opponents to software patent protection, the road to legislative change is at best uncertain.

This section considers drafting options and reasons to continue to prepare and at least permit publication of the application to create patent-defeating rights.

Recent patent-eligibility case law that has denied patent-eligibility includes *Bilski v. Kappos*, 561 U.S. 593 (2010)(software); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)(pharmaceutical method), the *Myriad* case, *Association for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013)(DNA patent-eligibility), and *Alice Corporation Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014)(software).

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As explained in *Bilski*, “an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.” *Bilski*, 561 U.S. at 611 (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)(emphasis supplied in *Bilski*). The two-tier statement first provides an open door to patent-eligibility but leaves the door opening to *patentability* that is limited to inventions that meet the requirements of Sections 102, 103 and 112.

Recent Supreme Court cases reaching a conclusion of lack of patent-eligibility under section 101 can be dealt with under the existing statutory framework for *patentability* under sections 102, 103 and 112. *Bilski* explains that “an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.” *Bilski v. Kappos*, 561 U.S. 593, 611 (2010)(quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)(emphasis supplied in *Bilski*). More completely, the Court said in *Bilski* that:

“[I]n [*Diamond v. Diehr*, 450 U.S. 175 (1981)], the Court established a limitation on the principles articulated in [*Gottschalk v. Benson*, 409 U.S. 63 (1972) and *Parker v. Flook*, 437 U.S. 584 (1978)]. The application in *Diehr* claimed a previously unknown method for ‘molding raw, uncured synthetic rubber into cured precision products,’ using a mathematical formula to complete some of its several steps by way of a computer. 450 U.S. at 177. *Diehr* explained that while an abstract idea, law of nature, or mathematical formula could not be patented, “an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.” *Id.* at 187. *Diehr* emphasized the need to consider the invention as a whole, rather than ‘dissect[ing] the claims into old and new elements and then . . . ignor[ing] the presence of the old elements in the analysis.’ *Id.* at 188. Finally, the Court concluded that because the claim was not “an attempt to patent a mathematical formula, but rather [was] an industrial process for the molding of rubber products,” it fell within § 101’s patentable subject matter. *Id.* at 192-93.”

Whether such *application* as in *Diehr* is *patentable* depends upon whether it meets the statutory *patentability* requirements of sections 102, 103 and 112. The *Bilski* invention under the Court's analysis clearly fell short of passing patentability muster. The same can be said for the invention in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2352 (2014) (“merely requiring generic computer implementation fails to transform that abstract idea into a patent-eligible invention.”).

C. The Current *Bilski* Era (2010 - ____)

Alice explains the *Benson* case in terms of “inventive concept”: , *Gottschalk v. Benson*, 409 U.S. 63 (1972): “Patent-eligibility in *Benson* was denied because “the computer implementation did not supply *the necessary **inventive concept***; the process could be ‘carried out in existing computers long in use.’” *Alice*, citing *Gottschalk v. Benson*, 409 U.S. 63, 64 (1972)(emphasis added).

Alice explains the *Diehr* case, 450 U.S. 175, 178 (1981): “[W]e held that a computer-implemented process for curing rubber was patent eligible, but not because it involved a computer. The claim employed a ‘well-known’ mathematical equation, but it used that equation in a process designed to solve a technological problem in ‘conventional industry practice.’” *Id.* quoting *Diamond v. Diehr*, 450 U.S. 175, 178 (1981).

In *Diehr*, although the claim employed what is described as a ‘well-known’ mathematical equation, there were additional steps included in the claim: “These additional steps, we recently explained, ‘transformed the process into an inventive application of the formula.’” *Alice*, 134 S.Ct. at 2358 (citation omitted). Or, “[i]n other words, the claims in *Diehr* were patent eligible because they improved an existing technological process, not because they were implemented on a computer.” *Alice*, 134 S.Ct. at 2358.

As explained in *Diehr*, “the Court [in *Parker v. Flook*, 437 U.S. 584 (1978),] explained the correct procedure for analyzing a patent claim employing a mathematical algorithm. Under this procedure, the algorithm is treated for § 101 purposes as though it were a familiar part of the prior art; the claim is then examined to determine whether it discloses ‘some other *inventive concept*.’” *Diehr*, 450 U.S. at 204(citing *Flook*, 437 U.S. at 591-95)(emphasis added; footnote deleted).

1. The *Mayo* “Step Two” Analysis

The Court in *Alice* denied patent-eligibility under 35 USC § 101 because the claimed invention lacks an “inventive feature”. *Alice* thus – for its *holding* – represents a complete overlap with the test for nonobviousness under 35 USC § 103. Thus, *Alice* characterizes the critical point in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), as whether there is an “inventive concept” present in the claimed invention, i.e., is the invention nonobvious under what is 35 USC § 103?

“At *Mayo* step two, we must examine the elements of the claim to determine whether it contains an ‘inventive concept’ sufficient to ‘transform’ the claimed abstract idea into a patent-eligible application.” *Alice*, 134 S.Ct. at 2357.

There is no hint or suggestion anywhere in *Alice* that patent-eligibility should be denied where there is an “inventive” feature – the synonym for nonobviousness. Thus, for example, “[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 (quoting *Mayo*).

Alice explains that patent-eligibility was denied in *Mayo* because the methods in *Mayo* “were already ‘well known in the art,’ and the process at issue amounted to “nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.’ ‘Simply appending conventional steps, specified *at a high level of generality*,’ was not ‘*enough*’ to supply an ‘inventive concept.’” *Alice*, 134 S.Ct. at 2357 (quoting *Mayo*)(emphasis added).

(To be sure, many inventions *made today* which recite software-implemented steps “at a high level of generality” may well be obvious *because of the state of the particular art at the time the invention was made*. But, for example, an invention made in, say, 1985, may well have been nonobvious with software implementation if a person skilled in the art would not have found such implementation obvious *at that time*.)

2. The Rigid *Mayo* “Apply It” Test

The “apply it” verbiage of *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), has been commonly employed in Federal Circuit jurisprudence. *See, e.g., CLS Bank Int'l v. Alice Corp.*, 717 F.3d 1269, 1291 (Fed. Cir. 2013)(en banc)(Lourie, J., joined by Dyk, Prost, Reyna, Wallach, JJ., concurring)(quoting *Mayo*, 132 S.Ct. at 1294), *subsequent proceedings, Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014)(“The system claims are [] akin to stating the abstract idea of third-party intermediation and adding the words: ‘apply it’ on a computer. *See Mayo*, 132 S.Ct. at 1294. That is not sufficient for patent eligibility, and the system claims before us fail to define patent-eligible subject matter under § 101, just as do the method and computer-readable medium claims.”); *Versata Dev. Grp., Inc. v. SAP Am., Inc.*, __ F.3d __, __ (Fed. Cir. 2015)(Plager, J.)(“[A] claim reciting an abstract idea must include additional features to ensure that the claim is more than a drafting effort designed to monopolize an abstract idea. [*Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014)]. This requires more than simply stating an abstract idea while adding the words ‘apply it’ or ‘apply it with a computer.’ *See id.* at 2358.”); *Intellectual Ventures I LLC v. Capital One Bank*, __ F.3d __, __ (Fed. Cir. 2015)(Dyk, J.)(“[T]here must be an ‘inventive concept’ to take the claim into the realm of patent-eligibility. [*Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014)].

A simple instruction to apply an abstract idea on a computer is not enough. . *Id.* at 2358. (“[M]ere recitation of a generic computer cannot transform a patent-ineligible idea into a patent-eligible invention. Stating an abstract idea ‘while adding the words ‘apply it’ is not enough for patent eligibility.’ (quoting *Mayo*, 132 S. Ct. at 1294)).”).

3. *Alice*, *Mayo Déjà vu*

In terms of the search for “inventive” subject matter *Alice* reprises the holding in *Diamond v. Diehr*, 450 U.S. 175 (1981). Clearly, *Alice* speaks in terms of whether or not the claimed subject matter is “inventive”, i.e., whether it is nonobvious.

Alice defines patent-eligibility under 35 USC § 101 for a claim with an abstract idea as requiring “inventiveness” or, as stated in *Alice*, the presence of “an inventive concept”. It is simply impossible to determine whether there is an “inventive concept” without an examination for nonobviousness. As stated in *Alice*:

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“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.’ [footnote omitted]

Alice explains the *Benson* case in terms of “inventive concept” , *Gottschalk v. Benson*, 409 U.S. 63 (1972): “Patent-eligibility in *Benson* was denied because “the computer implementation did not supply *the necessary inventive concept*; the process could be ‘carried out in existing computers long in use.’” *Alice*, citing *Gottschalk v. Benson*, 409 U.S. 63, 64 (1972)(emphasis added).

Alice explains the *Diehr* case, 450 U.S. 175, 178 (1981): “[W]e held that a computer-implemented process for curing rubber was patent eligible, but not because it involved a computer. The claim employed a ‘well-known’ mathematical equation, but it used that equation in a process designed to solve a technological problem in ‘conventional industry practice.’” *Id.* quoting *Diamond v. Diehr*, 450 U.S. 175, 178 (1981).

In *Diehr*, although the claim employed what is described as a ‘well-known’ mathematical equation, there were additional steps included in the claim: “These additional steps, we recently explained, ‘transformed the process into an inventive application of the formula.’” *Alice*, 134 S.Ct. at 2358 (citation omitted). Or, “[i]n other words, the claims in *Diehr* were patent eligible because they improved an existing technological process, not because they were implemented on a computer.” *Alice*, 134 S.Ct. at 2358.

As explained in *Diehr*, “the Court [in *Parker v. Flook*, 437 U.S. 584 (1978),] explained the correct procedure for analyzing a patent claim employing a mathematical algorithm. Under this procedure, the algorithm is treated for § 101 purposes as though it were a familiar part of the prior art; the claim is then examined to determine whether it discloses ‘some other *inventive concept*.’” *Diehr*, 450 U.S. at 204(citing *Flook*, 437 U.S. at 591-95)(emphasis added; footnote deleted).

4. Rigid v. Flexible Approaches, the Lesson of *KSR*

The rigid test keyed to *Mayo* and *Alice* creates an unworkable environment to provide a framework to judge patent-eligibility. *Ariosa* is the proof of the pudding that illustrates the fact that the rigid model of *Mayo* and *Alice* is broken.

The Court would do well to review its own criticism in *KSR* of the Federal Circuit’s rigid analytical scheme for determining nonobvious: “We begin by rejecting the rigid approach of the [Federal Circuit].” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007).

Wegner, *Patent Eligibility*

The Court needs to look in the mirror and weigh its own rigid patent-eligibility test against the metric of its criticism of the Federal Circuit’s rigid test for nonobviousness. “Throughout this Court’s engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the [Federal Circuit] applied its [teaching-suggestion-motivation] test here. *** [T]he principles laid down in *Graham* reaffirmed the ‘functional approach’ of *Hotchkiss* [*v. Greenwood*, 52 U.S. (11 How.) 248 (1851)]. To this end, *Graham* set forth a broad inquiry and invited courts, where appropriate, to look at any secondary considerations that would prove instructive. *Id.*, at 17.” *KSR*, 550 U.S. at 415.



VII. THE SPECIAL SIGNIFICANCE OF *CHAKRABARTY*

Diamond v. Chakrabarty, 447 U.S. 303 (1980), represented a milestone in the law of patent-eligibility, reconciling the disparate views expressed in divided opinions over the previous several decades starting with *Funk v. Kalo* and continuing through *Benson* and *Flook*. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948); *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Parker v. Flook*, 437 U.S. 584 (1978).

The opinion in *Chakrabarty* also needed to reconcile sharply differing views within the Court that had been badly split in *Flook*. The slim majority against patent-eligibility in *Flook* was flipped to create a 5-4 majority favoring patent-eligibility, a condition that continued for thirty years through *Diamond v. Diehr*, 450 U.S. 175 (1981), and *J.E.M. Ag Supply, Inc. v Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001), ending only with the notorious *Bilski v. Kappos*, 561 U.S. 593 (2010), spurred by a badly split appellate decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008)(en banc)(Michel, C.J.).

In any in depth consideration of *Chakrabarty* it is a useful starting point to consider the appellate decision affirmed by *Chakrabarty*. See *In re Bergy*, 596 F.2d 952, 966 (CCPA 1979)(Rich, J.), *aff'd as to Chakrabarty sub nom Diamond v. Chakrabarty*, 447 U.S. 303 (1980). In considering the precedential value of the *holding* of *Chakrabarty* it is useful to understand the issues that were raised on the petition for *certiorari* and what was actually decided in the *Chakrabarty* case.

A. “Inventive”, Unquestioned Nonobvious Subject Matter

The holding in *Chakrabarty* has nothing whatsoever to do with a definition of what is “inventive” or “nonobvious” subject matter because this was not even an issue raised in the petition for review and, indeed, was not a matter in controversy between the parties, Dr. Ananda Chakrabarty, the inventor, and Sidney Diamond, the head of the Patent Office.

The minimum bar for “inventive” activity to establish patent-eligibility was indeed nowhere discussed in *Chakrabarty*. Thus, subject matter that is “inventive” may *also* meet the higher standard of “markedly different characteristics” from a product of nature going beyond being “inventive” as in *Chakrabarty*, 447 U.S. at 309-10 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)) (“[The patent applicant’s] micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’ *** [T]he patentee has produced a new bacterium with *markedly different characteristics* from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101”)(emphasis added);

The “inventive” nature of the subject matter in *Chakrabarty* was unquestioned: There was no dispute as to the statutory issue of nonobviousness under 35 USC § 103. *See Bergy*, 596 F.2d at 966 (“[N]o formula, algorithm, or

law of nature is involved, and there has been no rejection on prior art of any kind ... [B]oth the examiner and the Board of Appeals expressly stated that no references evidencing prior art have been relied on or applied.”)

The “inventive” character of the invention in *Chakrabarty* is manifest as seen from the discussion by Judge Rich in the opinion below:

“Chakrabarty's [microorganisms] were engineered to solve [] one of man's practical needs, getting rid of oil spills. This they do by breaking down or ‘degrading’ the components of the oil into simpler substances which serve as food for aquatic life whereby the oil, assumed to be floating on the sea, is absorbed into it. * * * In essence what Chakrabarty invented was new strains of *Pseudomonas* having the new capability within themselves of degrading several different components of oil with the result that degradation occurs more rapidly. This he did by transmission into a single bacterial cell of a plurality of compatible “plasmids,” thereby creating the new strains. * * *

“To create his new strains of microorganisms, Chakrabarty started with a strain of *Pseudomonas aeruginosa*, which itself exhibited no capacity for degrading any component of oil. By a unique process, *** he transferred four plasmids, having the individual capabilities for degrading n-octane (a linear aliphatic hydrocarbon), camphor (a cyclic aliphatic hydrocarbon), salicylate (an aromatic hydrocarbon), and naphthalene (a polynuclear hydrocarbon), into the *Pseudomonas aeruginosa* bacterium that previously had none of the plasmids in question. This resulted in a new strain having new capacities to produce numerous enzymes to degrade four main components of oil.”

Bergy, 596 F.2d at 968-70.

Consistent with the appellate court majority opinion, the Court remarked on the nonobvious composition and properties:

“[Dr. Chakrabarty]’s micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally

occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’ *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887). The point is underscored dramatically by comparison of the invention here with that in *Funk* [*Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)]. There, the patentee had discovered that there existed in nature certain species of root-nodule bacteria which did not exert a mutually inhibitive effect on each other. He used that discovery to produce a mixed culture capable of inoculating the seeds of leguminous plants. Concluding that the patentee had discovered ‘only some of the handiwork of nature,’ the Court ruled the product nonpatentable:

“Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.’ 333 U.S. at 131.

“Here, by contrast, the patentee has produced a new bacterium with *markedly different characteristics* from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.”

Chakrabarty, 447 U.S. at 309-10 (emphasis added).

The statement that Dr. Chakrabarty’s invention has “markedly different characteristics”, is a confirmation of the scientific achievement of Dr. Chakrabarty and not a statement setting the minimum standards for patent eligibility. The fact that the *Chakrabarty* invention has “markedly different characteristics” manifests the fact that the invention is far above the minimum standard of an “inventive” or

nonobvious feature. Thus, it is only necessary to establish nonobviousness by showing difference in properties for a claimed composition if there is a case of *prima facie* obviousness.*

Thus, *Chakrabarty* did *not* set a minimum standard for what is or is not patent-eligible. Here, the presence of “markedly different characteristics” was found to be present and sufficient to meet patent-eligibility under 35 USC § 101. But, the Court never said that this was a *minimum* requirement for patent-eligibility

The question whether the subject matter is “inventive” is also that explained by Circuit Judge Bryson in the *Myriad* case, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1355 (Fed. Cir. 2012)(Bryson, J., dissenting in part), *subsequent proceedings sub nom Myriad* case, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013)(“Just as a

* Since the *Chakrabarty* invention is not even *prima facie* obvious, the fact that there are “markedly different characteristics” is unnecessary to establish that the subject matter is “inventive”, i.e., nonobvious.

“Markedly different characteristics” would only be necessary to *rebut* a case of *prima facie* obviousness under *Papesch*. *In re Dillon*, 919 F.2d 688, 696 (Fed. Cir. 1990)(en banc)(Lourie, J.)(“[T]he cases establish that if an examiner considers that he has found prior art close enough to the claimed invention to give one skilled in the relevant chemical art the motivation to make close relatives *** of the prior art compound(s), then there arises what has been called a presumption of obviousness or a *prima facie* case of obviousness. *In re Henze*, 181 F.2d 196 (CCPA 1950); *In re Hass*, 141 F.2d 122, 127, 130 (CCPA 1944). The burden then shifts to the applicant, who then can present arguments and/or data to show that what appears to be obvious, is not in fact that, when the invention is looked at as a whole. *In re Papesch*, 315 F.2d 381 (CCPA 1963).”)

patent involving a law of nature must have an ‘*inventive concept*’ that does ‘significantly more than simply describe ... natural relations,’ *Mayo [Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289, 1294, 1296 (2012)]*, a patent involving a product of nature should have an *inventive concept* that involves more than merely incidental changes to the naturally occurring product. In cases such as this one, in which the applicant claims a composition of matter that is nearly identical to a product of nature, it is appropriate to ask whether the applicant has done ‘enough’ to distinguish his alleged invention from the similar product of nature. Has the applicant made an ‘inventive’ contribution to the product of nature? Does the claimed composition involve more than ‘well-understood, routine, conventional’ elements?”(emphasis added)

Myriad is distinguished from *Chakrabarty* because “*Myriad* did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an *act of invention*.” *Myriad* case, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117 (2013)(emphasis added).

Whereas Dr. Chakrabarty’s invention was of a *new* microorganism crafted in the laboratory, one must contrast the aggregation of *known* microorganisms in *Funk v. Kalo*:

“In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, [333 U.S. 127 (1948)], the Court considered the validity of a patent to one Bond and the alleged infringement of a number of the patent's product claims. The subject matter involved certain naturally occurring bacteria of the genus *Rhizobium* which infect

the roots of leguminous plants and form nodules thereon hence enabling the plants to transform atmospheric nitrogen into organic nitrogenous compounds necessary for plant growth. It was well known that each species of these naturally occurring bacteria would only infect certain species of leguminous plants. Attempts (prior to Bond's work) to produce a useful mixture of bacteria, which farmers could use upon planting more than a single variety of plant, were unsuccessful. When mixed, different species of *Rhizobium* bacteria exhibited a mutually inhibiting effect and no suitable mixture had, therefore, been produced. Bond discovered that certain strains of the bacteria were not mutually inhibitive and he produced mixtures of the *Rhizobium* bacteria which mixtures were capable of inoculating multiple varieties of plants. Bond was granted a patent on his discovery. The Supreme Court found the following claim to be representative of Bond's invention:

“‘An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium*, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.’ *Id.*, 333 U.S. at 128 n. 1.

“Justice Douglas, speaking for a majority of the Court, said the following about Bond's claimed invention:

“ ‘We do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable. We have here only product claims. Bond does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. See *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1853). The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end. See *Telephone Cases*, 126 U.S. 1, 532-33 (1888); *DeForest Radio Co. v. General Electric Co.*, 283 U.S. 664, 684-85 (1931); *Mackey Radio & Tel. Co. v. Radio Corp.*, 306 U.S. 86 (1939); *Cameron Septic Tank Co. v. Saratoga Springs*, 159 F. 453, 462-63 (2nd Cir.). The Circuit Court of Appeals thought that Bond did much more than discover a law of nature,

since he made a new and different composition of non-inhibitive strains which contributed utility and economy to the manufacture and distribution of commercial inoculants. But we think that that aggregation of species fell short of invention within the meaning of the patent statutes.

“Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable. The aggregation of select strains of the several species into one product is an application of that newly-discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. *The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.* *id.* at 130-31.’ [emphasis added by Judge Rich].

“The Court held that ‘the product claims do not disclose an invention or discovery within the meaning of the patent statute.’ *Id.* at 132. This holding appears to arise, in part, from Bond's manner of claiming his invention, i. e., in terms of its property—non-inhibition—instead of claiming the precise constituent elements of his mixtures. The effect is an indirect, but nonetheless effective, monopoly over the phenomenon because the test for inclusion of a strain within the claim limits is the existence of the phenomenon.”

Bergy, at 993-94 (footnote omitted).

B. *Chakrabarty* “Combination” of Elements

Neither the Patent Office nor the Federal Circuit in a majority or dissenting opinion nor the Supreme Court in any opinion questioned the patent-eligibility of Dr. Chakrabarty’s claims to his nonobvious *combination* of his novel microorganism with the most conventional of second components, *straw*.

Straw!

Thus, one of the claims defines the invention as “[a]n inoculated medium * * * comprising [(a) straw] and [(b)] bacteria from the genus *Pseudomonas* carried thereby, at least some of said bacteria each containing at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway and said carrier material being able to absorb said hydrocarbon material.” *

C. *Funk v. Kalo* “Nature’s Secrets” Dicta

* Claim 31, rewritten in independent form:

Claim 30. “An inoculated medium for the degradation of liquid hydrocarbon substrate material floating on water, said inoculated medium comprising a carrier material able to float on water and bacteria from the genus *Pseudomonas* carried thereby, at least some of said bacteria each containing at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway and said carrier material being able to absorb said hydrocarbon material.”

Claim 31. “The inoculated medium of claim 30 wherein the carrier medium is straw.”

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Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948), was focused on the lack of a *patentable difference* for the claimed invention versus the prior art and not on patent-eligibility under what is today 35 USC § 101. See Jeffrey A. Lefstin, *Inventive Application: A History* (2014), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2398696; Lefstin & Menell, *amicus* brief in *Alice Corporation Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014), http://www.americanbar.org/content/dam/aba/publications/supreme_court_preview/briefs-v3/13-298_resp_amcu_profs-psm-jal.authcheckdam.pdf. See also Shine Tu, *Funk Brothers – an Exercise in Obviousness*, 80 UMKC L. Rev. 637, 637-38 (2012)).

In the *Bergy* case the late Giles Sutherland Rich explained the same point in the context of the Supreme Court *Flook* opinion:

“[W]e find in *Flook* an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated, namely, those pertaining to the *categories* of inventions in § 101 which *may* be patentable and to the *conditions* for patentability demanded by the statute for inventions within the statutory categories, particularly the nonobviousness condition of § 103.

The confusion creeps in through such phrases as ‘eligible for patent protection,’ ‘patentable process,’ ‘new and useful,’ ‘inventive application,’ ‘inventive concept,’ and ‘patentable invention.’ The last mentioned term is perhaps one of the most difficult to deal with unless it is used *exclusively* with reference to an invention which complies with *every* condition of the patent statutes so that a valid patent may be issued on it.”

In re Bergy, 596 F.2d 952, 959 (CCPA 1979), *aff’d sub nom Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

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For one year short of a full quarter century, *Funk v. Kalo* was a relatively obscure case holding that an aggregation of bacterial was obvious or – to use the terminology before the 1952 Patent Act – lacked “patentable invention”. Twenty-four years later the author of the *Benson* case latched onto *dicta* from his previous majority opinion in *Funk v. Kalo* as basis for sweeping statements denying patent-eligibility to software technology.

The Bond invention claimed in *Funk v. Kalo* is to a classic “manufacture” or “article of manufacture”, a novel mixture of bacterial: “An inoculant ... comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium*....” *Funk v. Kalo*, 333 U.S. at 128 n.1 (quoting claim 4).

Indeed, the Court recognizes that Bond’s mixture is a “new and different *composition*”:

“The Circuit Court of Appeals [in its ruling sustaining patent validity] thought that Bond did much more than discover a law of nature, since he made a new and different composition of non-inhibitive strains which contributed utility and economy to the manufacture and distribution of commercial inoculants.” *Funk v. Kalo*, 333 U.S. at 130-31.

The *holding* in *Funk v. Kalo* was that this combination lacked “invention” – the pre-1952 *Hotchkiss*-based wording of the day for the standard of what four years later under the 1952 Patent Act was codified as a standard of nonobviousness under what today is 35 USC § 103(a).

Wegner, *Patent Eligibility*

The *holding* in *Funk v. Kalo* focused upon “invention” in the sense of obviousness as stated by the Court itself: Bond’s “*aggregation of species* fell short of invention within the meaning of the patent statutes.” More completely stated:

“The Circuit Court of Appeals [in its ruling sustaining patent validity] thought that Bond did much more than discover a law of nature, since he made a new and different composition of non-inhibitive strains which contributed utility and economy to the manufacture and distribution of commercial inoculants. But we think that that *aggregation of species* fell short of invention within the meaning of the patent statutes.”

Funk v. Kalo, 333 U.S. at 130-31 (emphasis added).

The focus on obviousness is underscored by the concurring opinion of Justice Frankfurter: “Insofar as the court below concluded that the packaging of a particular mixture of compatible strains is an invention [in the sense of patent-eligibility] and as such patentable, I agree, provided not only that a new and useful property results from their combination, but also that *the particular strains are identifiable and adequately identified.*” *Funk v. Kalo*, 333 U.S. at 133 (Frankfurter, J., concurring)(emphasis added). He points out that the Bond claim failed to *identify* the particular strains which were basis for the claim of his unobvious result.

The majority attributes the beneficial results of the patentee’s work to “nature”: “Bond does not create a state of inhibition or of non-inhibition in the bacteria. Their *qualities are the work of nature*. Those qualities are of course not patentable.”

Wegner, *Patent Eligibility*

Manifesting his knowledge of science *vel non* Justice Douglas states:

“Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable. The aggregation of select strains of the several species into one product is an application of that newly-discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. . . . The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.”

Funk v. Kalo, 333 U.S. at 130.

The quoted statement of opinion relates not to the law but to the relation of science to a mystical belief of nature and has been outdistanced by the growth of scientific knowledge:

D. *Myriad* Characterization of *Chakrabarty*

More than thirty years removed from *Chakrabarty* the case has been reconsidered anew in the *Myriad* case, both at the Federal Circuit, *Association for Molecular Pathology v. United States Patent and Trademark Office*, 689 F.3d 1303, 1337-39 (Fed. Cir. 2012), and at the Supreme Court, *Association for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013).

Wegner, *Patent Eligibility*

Leading up to *Chakrabarty*, it was understood that compositions based upon natural products have long been considered both patent-eligible under Section 101 and “inventive” or nonobvious under what is now Section 103. See *In re Bergy*, 596 F.2d 952, 996 n.4 (CCPA 1979), *aff’d sub nom Diamond v. Chakrabarty*, 447 U.S. 303 (1980)(“[T]he patentability of purified naturally occurring products [have been] found [] generally to be within the purview of § 101 or its predecessors. See *In re Bergstrom*, 427 F.2d 1394 (1970) (prostaglandin compounds); *Merck v. Olin Mathieson Chemical*, 253 F.2d 156 (4th Cir. 1958) and *Merck v. Chase Chemical*, 273 F.Supp. 68 (D.N.J.1967) (Vitamin B-12); *Sterling Drug v. Watson, Comr. Pats.*, 135 F.Supp. 173 (D.C.D.C.1955) (1-arterenol); *Parke-Davis v. Mulford*, 196 F. 496 (2d Cir. 1912) (adrenalin).”). Statements in *Bergy* must now, of course, be considered in light of the *Myriad* case, *Association for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013).

1. The Issue Decided in *Myriad*

A useful introduction to *Chakrabarty* is provided by Circuit Judge Moore in her concurrence in part in the appellate proceedings:

“The Patent Act, 35 U.S.C. § 101, allows ‘[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof’ to obtain a patent. The plain language of this statute only requires that an invention be ‘new and useful,’ and fall into one of four categories: a ‘process, machine, manufacture, or composition of matter.’ ‘Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’ ‘*Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting the statutory history).

“While the plain language used by Congress did not limit the scope of patentable subject matter in the statute, the ‘Court’s precedents provide three specific exceptions to § 101’s broad patent-eligibility principles: ‘laws of nature, physical phenomena, and abstract ideas.’ ‘*Bilski v. Kappos*, 130 S.Ct. 3218, 3226 (2010) (quoting *Chakrabarty*, 447 U.S. at 309, 100 S.Ct. 2204). These exceptions ‘rest [], not on the notion that natural phenomena are not processes [or other articulated statutory categories], but rather on the more fundamental understanding that they are not the kind of ‘discoveries’ that the statute was enacted to protect.’ *Parker v. Flook*, 437 U.S. 584, 593 (1978).

“Applying the judicially created exception to the otherwise broad demarcation of statutory subject matter in section 101 can be difficult. *See Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 134–35 (1948) (Frankfurter, J., concurring) (‘[S]uch terms as ‘the work of nature’ and the ‘laws of nature’ ... are vague and malleable.... Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.’). The analysis is relatively simple if the invention previously existed in nature exactly as claimed. For example, naturally existing minerals, a plant found in the wild, and physical laws such as gravity or $E=mc^2$ are not patentable subject matter, even if they were ‘discovered’ by an enterprising inventor. *Chakrabarty*, 447 U.S. at 309.

Even when an invention does not exist in nature in the claimed state, it may still be directed to subject matter that is not patentable. For example, in *Funk Brothers*, the Supreme Court held a patent to a combination of multiple naturally occurring bacterial strains was not patentable. Although there was ‘an advantage in the combination,’ which was apparently ‘new and useful,’ none of the bacterial strains ‘acquire[ed] a different use’ in combination. *Funk Bros.*, 333 U.S. at 131–32. The aggregation of the bacterial strains into a single product produced ‘no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way.... They serve the ends nature originally provided and act quite independently of any effort of the patentee.’ *Id.*

In contrast, the Supreme Court held bacteria that included extra genetic material introduced by the inventor were ‘a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use’ ‘and therefore patentable. *Chakrabarty*, 447 U.S. at 309–10

(quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)). *Chakrabarty* explained that there is no distinction between inventions based on living and inanimate objects for the purpose of the patent statute; instead, the ‘relevant distinction’ for the section 101 analysis is ‘between products of nature ... and human-made inventions.’ *Id.* at 312–13. Even if the invention was based on nature, and resulted in a living organism, it may fall within the scope of section 101. For example, ‘the work of the plant breeder ‘in aid of nature’ was patentable invention’ because ‘a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man.’ ‘*Id.* (quoting S.Rep. No. 315, 71st Cong., 2d Sess., 6–8 (1930)). In *Chakrabarty*, the intervention of man resulted in bacteria with ‘markedly different characteristics’ from nature and ‘the potential for significant utility,’ resulting in patentable subject matter. *Id.* at 310.

“*Funk Brothers* and *Chakrabarty* do not stake out the exact bounds of patentable subject matter. Instead, each applies a flexible test to the specific question presented in order to determine whether the claimed invention falls within one of the judicial exceptions to patentability. *Funk Brothers* indicates that an invention which ‘serve[s] the ends nature originally provided’ is likely unpatentable subject matter, but an invention that is an ‘enlargement of the range of ... utility’ as compared to nature may be patentable. 333 U.S. at 131. Likewise, *Chakrabarty* illustrates that an invention with a distinctive name, character, and use, e.g., markedly different characteristics with the potential for significant utility, is patentable subject matter. 447 U.S. at 309–10. Although the two cases result in different outcomes, the inquiry itself is similar.

“Courts applied an analogous patentability inquiry long before *Funk Brothers* or *Chakrabarty*. In one notable case, Judge Learned Hand held that purified adrenaline, a natural product, was patentable subject matter. Judge Hand explained that even if the claimed purified adrenaline were ‘merely an extracted product without change, there is no rule that such products are not patentable.’ *Parke–Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y.1911). This is because ‘while it is of course possible logically to call this a purification of the principle’ the resulting purified adrenaline was ‘for every practical purpose a new thing commercially and therapeutically.’ *Id.* Similarly, in a case applying the Patent Act of 1952,¹ purified vitamin B–12, another natural product, was also held patentable subject matter within the meaning of section 101. *Merck & Co. v. Olin Mathieson*

Chem. Corp., 253 F.2d 156 (4th Cir.1958). The Fourth Circuit explained that purified vitamin B–12 was ‘far from the premise of the [naturally occurring] principle.... The new product, not just the method, had such advantageous characteristics as to replace the [naturally occurring] liver products. What was produced was, in no sense, an old product.’ *Id.* at 162–63. These purified pharmaceutical cases are both consistent with Supreme Court precedent: the purified substance was ‘a new thing ... therapeutically,’ *Parke–Davis*, 189 F. at 103, and had such ‘advantageous characteristics’ that what was produced by purification ‘was, in no sense, an old product.’ *Merck*, 253 F.2d at 162–63. In other words, the purified natural products were held to have ‘markedly different characteristics,’ as compared to the impure products, which resulted in ‘the potential for significant utility.’ *Chakrabarty*, 447 U.S. at 310.

“In contrast, mere purification of a naturally occurring element is typically insufficient to make it patentable subject matter. For example, our predecessor court held that claims to purified vanadium and purified uranium were not patentable subject matter since these were naturally occurring elements with inherent physical properties unchanged upon purification. *See In re Marden*, 47 F.2d 958, 959 (CCPA 1931) (‘[P]ure vanadium is not new in the inventive sense, and, it being a product of nature, no one is entitled to a monopoly of the same.’); *In re Marden*, 47 F.2d 957 (CCPA 1931) (‘ductile uranium’ not patentable because uranium is inherently ductile). Likewise, claims to purified ductile tungsten were not patentable subject matter since pure tungsten existed in nature and was inherently ductile. *General Electric Co. v. De Forest Radio Co.*, 28 F.2d 641, 643 (3d Cir.1928). In each of these cases, purification did not result in an element with new properties. Instead, the court held the naturally occurring element inherently had the same characteristics and utility (e.g. ductility) as the claimed invention. Consistent with *Funk Brothers* and *Chakrabarty*, the claims all fell within the laws of nature exception.

“As illustrated by these examples, courts have long applied the principles articulated in *Funk Brothers* and *Chakrabarty* to different factual scenarios in order to determine whether an invention, as claimed, falls into the laws of nature exception.

Association for Molecular Pathology, 689 F.3d at 1337-39 (Moore, J., concurring in part), *subsequent proceedings*, *Association for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013).

On appeal, the Supreme Court modified the Federal Circuit ruling:

Section 101 of the Patent Act provides:

“Whoever invents or discovers any new and useful ... composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101.

We have “long held that this provision contains an important implicit exception[:]
Laws of nature, natural phenomena, and abstract ideas are not patentable.” *Mayo*, 132 S.Ct., at 1293 (internal quotation marks and brackets omitted). Rather, “‘they are the basic tools of scientific and technological work’ ” that lie beyond the domain of patent protection. *Id.*, 132 S.Ct. at 1293. As the Court has explained, without this exception, there would be considerable danger that the grant of patents would “tie up” the use of such tools and thereby “inhibit future innovation premised upon them.” *Id.*, 132 S.Ct., at 1301. This would be at odds with the very point of patents, which exist to promote creation. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (Products of nature are not created, and “‘manifestations ... of nature [are] free to all men and reserved exclusively to none’ ”).

The rule against patents on naturally occurring things is not without limits, however, for “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,” and “too broad an interpretation of this exclusionary principle could eviscerate patent law.” 132 S.Ct. at 1293. As we have recognized before, patent protection strikes a delicate balance between creating “incentives that lead to creation, invention, and discovery” and “imped[ing] the flow of information that might permit, indeed spur, invention.” *Id.*, 132 S.Ct., at 1305. We must apply this well-established standard to determine whether Myriad's patents claim any “new and useful ... composition of matter,” § 101, or instead claim naturally occurring phenomena.

B

It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. Instead, Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13. The question is whether this renders the genes patentable.

Myriad recognizes that our decision in *Chakrabarty* is central to this inquiry. Brief for Respondents 14, 23–27. In *Chakrabarty*, scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil. 447 U.S. at 305 and n. 1. The Court held that the modified bacterium was patentable. It explained that the patent claim was “not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’ ” *Id.*, at 309–310 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887); alteration in original). The *Chakrabarty* bacterium was new “with markedly different characteristics from any found in nature,” 447 U.S. at 310, due to the additional plasmids and resultant “capacity for degrading oil.” *Id.*, at 305, n. 1. In this case, by contrast, Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.

Association for Molecular Pathology v. Myriad, 133 S. Ct. at 2116–17.

2. “Unique” Structural Modifications

The Supreme Court in *Myriad* did *not* rule on the patent eligibility of molecules that are “unique”: “If the [Myriad] patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad's patent claims on entire genes [as defined in their claims] by isolating a DNA sequence that included both the [genes found in nature] and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule

‘invented’ by Myriad.” *Association for Molecular Pathology v. Myriad*, 133 S. Ct. at 2118.

3. cDNA is Not a “Product of Nature”

As explained in *Myriad*, “the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a ‘product of nature’ and is patent eligible under § 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA.” *Association for Molecular Pathology v. Myriad*, 133 S. Ct. at 2119.

4. “Applications” of the Newly Discovered Gene Sequence

As stated in *Myriad*, “this case does not involve patents on new *applications* of knowledge about the [genes found in nature]. Judge Bryson aptly noted that, ‘[a]s the first party with knowledge of the [natural gene] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications.’” *Association for Molecular Pathology v. Myriad*, 133 S. Ct. at 2120 (quoting *Association for Molecular Pathology*, 689 F.3d at 1349)(Bryson, J.))

5. Altered Gene Sequences

“[We do not] consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application

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of § 101 to such endeavors. We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.” *Association for Molecular Pathology v. Myriad*, 133 S. Ct. at 2120.

Particularly in earlier centuries and millennia but still well into the twentieth century, where there is no scientific explanation for a phenomenon, the explanation was often that this was a “nature’s secret”. As the frontiers of science rolled back the areas of uncertainties, what had been “nature’s secret” was now attributable to a rational scientific explanation.

One of the last bastions of a mystical belief in “nature’s secrets” relates to the explanation of mechanisms of pharmaceutical and agricultural phenomena where there is no explanation available from science.

One may see the spread of science filling the void of knowledge in the field of cancer treatments. Whereas little more than a generation ago a diagnosis of cancer was usually a diagnosis of impending death, whereas today more and more cancers are treatable and in some areas the prognosis for recovery outweighs the alternative. Yet, specific cancer treatments remain elusive as only one out of literally thousands of compounds has true efficacy in humans and many cancers remain untreatable.



VIII. *EN BANC*-WORTHY ISSUES WITHIN *ARIOSA*

The *Ariosa* case is a patent piñata having a host of issues that are *en banc*-worthy, coupled with the fact that the DNA technology involved in the case is very easy to understand from the standpoint of the legal issues. There should thus be a great temptation for grant of *en banc* review at the Federal Circuit and, at the technologically-challenged Supreme Court, grant of *certiorari* at the highest court.

The extreme nature of *Ariosa* is explained in the concurring opinion by the elder member of the panel:

“*** I am bound by the sweeping language of the test set out in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). In my view, the breadth of the second part of the test was unnecessary to the decision reached in *Mayo*. This case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain.

“It has long been established that ‘[l]aws of nature, natural phenomena, and abstract ideas are not patentable.’ *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014) (citations omitted). In *Mayo*, the Supreme Court set forth a two-step framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. The first step looks to determine whether claims are directed to a patent-ineligible concept. *Mayo*, 132 S. Ct. at 1297. If they are, the second step is to consider whether the additional elements recited in the claim ‘transform the nature of the claim’ into a patent-eligible application by reciting an ‘inventive concept’ that is ‘sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.’ *Id.* at 1294.

“In applying the second part of the test, the Supreme Court in *Mayo* discounted, seemingly without qualification, any ‘[p]ost-solution activity that is purely conventional or obvious,’ *id.* at 1299 (original alterations omitted). This was

unnecessary in *Mayo*, because doctors were already performing in combination all of the claimed steps of administering the drug at issue, measuring metabolite levels, and adjusting dosing based on the metabolite levels, *id.*

“In *Diamond v. Diehr*, the Supreme Court held that ‘a new combination of steps in a process may be patentable even though all the constituents of the combination were well-known and in common use before the combination was made.’ 450 U.S. 175, 188 (1981). As *Mayo* explained: *Diehr* ‘pointed out that the basic mathematical equation, like a law of nature, was not patentable. But [*Diehr*] found the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole.’ *Mayo* 132 S. Ct. at 1298. Despite that recognition, *Mayo* discounted entirely the ‘conventional activity’ recited in the claims in that case because the steps ‘add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field.’ *Id.* at 1299. While that conclusion might have been warranted in that case, given the fact that the ‘conventional activities’ in *Mayo* were the very steps that doctors were already doing—administering the drug at issue, measuring metabolite levels, and adjusting dosing based on the metabolite levels—the Supreme Court did not limit its ruling to those particular facts and circumstances.

“The Supreme Court's blanket dismissal of conventional post-solution steps leaves no room to distinguish *Mayo* from this case, even though here *no one* was amplifying and detecting paternally-inherited [cell-free fetal DNA] using the plasma or serum of pregnant mothers. Indeed, the maternal plasma used to be ‘routinely discarded,’ ‘540 patent col.1 ll.50-53, because, as Dr. Evans testified, ‘nobody thought that fetal cell-free DNA would be present.’

“It is hard to deny that [the] invention is truly meritorious. Prior to the ‘540 patent, prenatal diagnoses required invasive methods, which ‘present[ed] a degree of risk to the mother and to the pregnancy.’ *Id.* at col.1 ll. 16—17. The available ‘techniques [we]re time-consuming or require[d] expensive equipment.’ *Id.* at col.1 ll.17—37. Dr. Mark Evans testified that ‘despite years of trying by multiple methods, no one was ever able to achieve acceptable success and accuracy.’ In a groundbreaking invention, Drs. Lo and Wainscoat discovered that there was cell-free fetal DNA in the maternal plasma. The Royal Society lauded this discovery as ‘a paradigm shift in non-invasive prenatal diagnosis,’ and the inventors' article

describing this invention has been cited well over a thousand times. The commercial embodiment of the invention, the MaterniT21 test, was the first marketed non-invasive prenatal diagnostic test for fetal aneuploidies, such as Down's syndrome, and presented fewer risks and a more dependable rate of abnormality detection than other tests. Unlike in *Mayo*, the '540 patent claims a new method that should be patent eligible. While the instructions in the claims at issue in *Mayo* had been widely used by doctors—they had been measuring metabolites and recalculating dosages based on toxicity/inefficacy limits for years—here, the amplification and detection of [cell-free fetal DNA] had never before been done. The new use of the previously discarded maternal plasma to achieve such an advantageous result is deserving of patent protection. Cf. Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 Yale L.J. Online 341, 343-44 (2013) (noting that despite *Mayo*'s declaration that a claim to ‘a new way of using an existing drug’ is patentable, *Mayo*, 132 S. Ct. at 1302, it is unclear how a claim to new uses for existing drugs would survive *Mayo*'s sweeping test).

“In short, [the] invention is nothing like the invention at issue in *Mayo*. [The patentees] ‘effectuate[d] a practical result and benefit not previously attained,’ so its patent would traditionally have been valid. *Le Roy v. Tatham*, 63 U.S. 132, 135-36 (1859) (quoting *Househill Coal & Iron Co. v. Neilson*, Webster's Patent Case 673, 683 (House of Lords 1843)); *Le Roy v. Tatham*, 55 U.S. 156, 175 [(1853)] (same); see generally Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. (forthcoming 2015), available at <http://ssrn.com/abstract=2398696> (last visited June 10, 2015) (analyzing traditional notions of patent eligibility of newly discovered laws of nature). But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.

Ariosa, __ F.3d at __ (Linn, J., concurring).

There are at least three important issues within the *Ariosa* opinion that are *en banc*-worthy:

A. “Inventive” Subject Matter Lacking Patent-Eligibility

1. *Ariosa* Breaks the *Mayo* Patent-Eligibility Mold

Is there subject matter that is “inventive” – nonobvious under 35 USC § 103 – that somehow lacks patent-eligibility under 35 USC § 101?

Ariosa represents a classic case of an invention that is to pioneer, breakthrough subject matter and, *a fortiori*, an invention that clearly and unequivocally has an “inventive” step whether under the classic case law of *Hotchkiss* or its codification as nonobviousness under 35 USC § 103. To the extent that the *Mayo* test for determining patent-eligibility leads to the conclusion that “inventive” subject matter such as in *Ariosa* can lack patent-eligibility manifests the fact that the *Mayo* formulation is too rigid and offers nothing to determine whether to grant a patent to “inventive” subject matter that is not safely determined within the friendly confines of statutory nonobviousness under 35 USC §103.

Ariosa demonstrates that the *Mayo dicta* that has created an amorphous body of case law under 35 USC § 101 that is entirely unnecessary. The conclusion to draw from *Ariosa* is that the invention *is* “inventive” and hence patent-eligible – even if it does not follow the *Mayo dicta*.

Two critical shortcomings are apparent from *Ariosa*. Patent-eligibility should be determined by (a) first reading an entire claim *as a whole* to give weight to “all elements” of the claim to determine the metes and bounds of protection;

and (b) then determining whether the *overall claimed combination*, is “inventive”, which should end the inquiry. In this latter regard concerning the *overall claimed combination* it is often the *combination* that is “inventive”, whereas the component elements, individually, may all lack patent-eligibility, standing *in vacuo* apart from the claimed combination.

2. Pioneer, Breakthrough “Inventive” Subject Matter in *Ariosa*

The majority opinion in *Ariosa* demonstrates just how far the Federal Circuit has interpreted the dicta from *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), to the point that the Federal Circuit runs counter to other Supreme Court precedent such as the *Adams Battery* case, *United States v. Adams*, 383 U.S. 39 (1966), as well as its own precedent such as *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995), and *In re Brouwer*, 77 F.3d 422 (Fed. Cir. 1996).

In *Ariosa* the majority issued perhaps its most extreme application of *dicta* in *Mayo* to deny patent-eligibility of truly “inventive” subject matter where it was now possible to test for genetic conditions in a fetus simply by drawing blood from the mother without invasive testing of an amniotic fluid sample, a most remarkable breakthrough discovery. “In 1996, [the patentees] Drs. Dennis Lo and James Wainscoat discovered cell-free fetal DNA [] in maternal plasma and serum, the portion of maternal blood samples that other researchers had previously discarded as medical waste. [Cell-free fetal DNA] is non-cellular fetal DNA that circulates freely in the blood stream of a pregnant woman.” *Ariosa*, ___ F.3d at ___.

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The minute amount of fetal DNA in the mother's bloodstream could not have been basis for genetic testing years ago, but with the discovery that minute amounts of such fetal DNA are present in the maternal bloodstream permitted use of "polymerase chain reaction ("PCR") [which is] a widely used technique in molecular biology that was invented by Kary Mullis in 1983. Indeed, in 1993, Mullis won the Nobel Prize in Chemistry for his development of PCR[.]” *Carnegie Mellon University v. Hoffmann-La Roche, Inc.*, 541 F.3d 1115, 1129 n.4 (Fed. Cir. 2008).

Claim 1 of the patent in *Ariosa* is to “[a] method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises [(a)] *amplifying a paternally inherited nucleic acid* from the serum or plasma sample[;] and[(b)] detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.” *Ariosa*, __ F.3d at __ (emphasis added).

The extreme nature of *Ariosa* is explained in the concurring opinion by the elder member of the panel:

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discarded,’ '540 patent col.1 ll.50-53, because, as Dr. Evans testified, ‘nobody thought that fetal cell-free DNA would be present.’

“It is hard to deny that [the] invention is truly meritorious. Prior to the '540 patent, prenatal diagnoses required invasive methods, which ‘present[ed] a degree of risk to the mother and to the pregnancy.’ *Id.* at col.1 ll. 16—17. The available ‘techniques [we]re time-consuming or require[d] expensive equipment.’ *Id.* at col.1 ll.17—37. Dr. Mark Evans testified that ‘despite years of trying by multiple methods, no one was ever able to achieve acceptable success and accuracy.’ In a groundbreaking invention, Drs. Lo and Wainscoat discovered that there was cell-free fetal DNA in the maternal plasma. The Royal Society lauded this discovery as ‘a paradigm shift in non-invasive prenatal diagnosis,’ and the inventors' article describing this invention has been cited well over a thousand times. The commercial embodiment of the invention, the MaterniT21 test, was the first marketed non-invasive prenatal diagnostic test for fetal aneuploidies, such as Down's syndrome, and presented fewer risks and a more dependable rate of abnormality detection than other tests. Unlike in *Mayo*, the '540 patent claims a new method that should be patent eligible. While the instructions in the claims at issue in *Mayo* had been widely used by doctors—they had been measuring metabolites and recalculating dosages based on toxicity/inefficacy limits for years—here, the amplification and detection of [cell-free fetal DNA] had never before been done. The new use of the previously discarded maternal plasma to achieve such an advantageous result is deserving of patent protection. *Cf.* Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 Yale L.J. Online 341, 343-44 (2013) (noting that despite *Mayo*'s declaration that a claim to ‘a new way of using an existing drug’ is patentable, *Mayo*, 132 S. Ct. at 1302, it is unclear how a claim to new uses for existing drugs would survive *Mayo*'s sweeping test).

“In short, [the] invention is nothing like the invention at issue in *Mayo*. [The patentees] ‘effectuate[d] a practical result and benefit not previously attained,’ so its patent would traditionally have been valid. *Le Roy v. Tatham*, 63 U.S. 132, 135-36 (1859) (quoting *Househill Coal & Iron Co. v. Neilson*, Webster's Patent Case 673, 683 (House of Lords 1843)); *Le Roy v. Tatham*, 55 U.S. 156, 175 [(1853)] (same); see generally Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. (forthcoming 2015), available at <http://ssrn.com/abstract=2398696> (last visited June 10, 2015) (analyzing traditional notions of patent eligibility of newly

discovered laws of nature). But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.

Ariosa, ___ F.3d at ___(Linn, J., concurring).

3. Intra-Circuit Split over Scope of Patent Eligibility

The Federal Circuit has yet to provide a uniform answer to the following issue: Is there “inventive” subject matter – subject matter that is thus “nonobvious” under 35 USC § 103 – yet can such “inventive” subject matter lack patent-eligibility under 35 USC § 101?

The Federal Circuit is badly split on this issue: Five of its members have said that the test is whether there is a “*significant* ‘inventive concept.’” *CLS Bank Int’l v. Alice Corp.*, 717 F.3d 1269, 1291 (Fed. Cir. 2013)(en banc)(Lourie, J., joined by Dyk, Prost, Reyna, Wallach, JJ., concurring)(quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012)), *subsequent proceedings, Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014).

B. Patent-Eligibility Keyed to the Invention As a Whole

Should the presence of “inventive” subject matter be based upon “all elements” of the claimed subject matter consistent with nineteenth century foundational “all elements” case law or may the presence of an “abstract” or other

section 101 subject matter as an *element* of the claimed invention be basis to deny patent-eligibility of the invention as claimed?

Is it proper to ignore the nonobviousness of the invention *as a whole* in determining whether there is an “inventive” step or – as in *Adams Battery* – nonobviousness of the overall combination claims?

These are yet further issues found in the *Ariosa* case.

Thus, at some point the Federal Circuit needs to resolve the issue whether the claimed invention *as a whole* should be evaluated as to whether there is an “inventive” step, as opposed to dissection of the claim to reach a conclusion of lack of patent-eligibility where one of the elements of the invention, standing alone, lacks patent-eligibility.

1. *Flook* versus the “All Elements” Rule

Attempts to reconcile the dissection of the claim in *Parker v. Flook* with the later *Diamond v. Diehr* must be seen from the standpoint that the later *Diehr* distinguished and thus limited *Flook*.

Furthermore, taking *dicta* from *Mayo in vacuo* leads to an unnecessary conflict within the case law of the Supreme Court that has uniformly required consideration of the invention as a whole, “all elements” of the claimed invention in their combination defined by the patentee. In the context of patent infringement, the cases repeatedly spoke of the judicial requirement to construe the subject matter under the “all elements” rule. There is a rich history of precedent more from more than one hundred years ago that established the rule that was

established by Justice Story. See *Barrett v. Hall*, 2 F.Cas. 914, 924 (No. 1047)(D. Mass. 1818)(Story, J., riding circuit)(“the patent [is] for the combination only[;] it is no infringement of the patent to use any of the machines separately, if the whole combination be not used; for in such a case the thing patented is not the separate machines, but the combination; and the statute gives no remedy, except for a violation of the thing patented.”); see also *Prouty v. Draper*, 20 F.Cas. 11, 12 (No. 11,446) (D. Mass. 1841)(Story, J.; riding circuit), *aff’d*, 41 U.S. (16 Pet.) 336 (1842)(Taney, C.J.)(“ “The plaintiffs' patent is for an entire combination of all the three things, and not for a combination of any two of them. A patent for a combination of A, B and C, cannot be technically or legally deemed at once a combination of A, B and C, and of A and B alone.”); *Eames v. Godfrey*, 68 U.S. (1 Wall.) 78, 79 (1864)(“[T]here is no infringement of a patent which claims mechanical powers in combination unless all the parts have been substantially used. The use of a part less than the whole is no infringement.”); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 335-37 (1879)(“It is a well-known doctrine of patent law, that the claim of a combination is not infringed if any of the material parts of the combination are omitted. ***”).

The quoted cases are merely illustrative of the many “all elements” cases from the nineteenth century that include, *inter alia*, *Vance v. Campbell*, 66 U.S. (1 Black) 427, 429 (1861); *Eames v. Godfrey*, 68 U.S. (1 Wall.) 78, 79 (1864); *Gould v. Rees*, 82 U.S. (15 Wall.) 187 (1872); *Dunbar v. Myers*, 94 U.S. (4 Otto) 187, 202 (1876); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 335-37 (1879); *Case v. Brown*, 69 U.S. (2 Wall.) 320, 327-28 (1864); *Gill v. Wells*, 89 U.S. (22 Wall.) 1, 26-30 (1874); *Fuller v. Yentzer*, 94 U.S. (4 Otto) 288, 297 (1876); *Gage*

v. Herring, 107 U.S. (17 Otto) 640, 648 (1882); *Fay v. Cordesman*, 109 U.S. 408, 420-21 (1883); *Rowell v. Lindsay*, 113 U.S. 97, 102 (1885); *Sargent v. Hall Safe & Lock Co.*, 114 U.S. 63, 86 (1885); *Brown v. Davis*, 116 U.S. 237, 252 (1886); *Yale Lock Mfg. Co. v. Sargent*, 117 U.S. 373, 378 (1886); *McClain v. Ortmyer*, 141 U.S. 419, 425 (1891); *Wright v. Yuengling*, 155 U.S. 47, 52 (1894); *Black Diamond Coal Mining Co. v. Excelsior Coal Co.*, 156 U.S. 611, 617-18 (1895); *Cimiotti Unhairing Co. v. American Fur Ref. Co.*, 198 U.S. 399, 410 (1905)).

2. The “Inventive” Feature of the *Claimed Combination*

Claimed subject matter to a combination invention is “inventive” – or nonobvious under the 1952 Patent Act – where the *combination* is nonobvious. Thus, even though each of the components of the claimed invention may lack novelty, a critical question of inventiveness or nonobviousness of the claim to the combination is whether or not there is *motivation* to create the claimed combination.

It is axiomatic that the patentability of a *claim* to a *combination* of elements must be judged in terms of the *claimed combination* including all of its elements and – particularly – the determination whether there is *motivation* to combine the several elements in the manner *stated in the claim*.

Whether subject matter to a combination invention is “inventive” – or nonobvious under the 1952 Patent Act – where the *combination* is nonobvious cannot be based simply upon eligibility of the component elements of the

combination. Thus, even though each of the components of the claimed invention may lack novelty, a critical question of inventiveness or nonobviousness of the claim to the combination is whether or not there is *motivation* to create the claimed combination.

It is fundamental that the *claimed invention* including all of its elements should be evaluated and not dissected element by element. *See § IV-A, The Invention “As a Whole”*. Thus, ““it is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention[.]” *Id.*(quoting *Adams Battery* case, *United States v. Adams*, 383 U.S. 39, 48-49 (1966)(citing *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 547 (1871); *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 312 U.S. 654 (1940); *Schering Corp. v. Gilbert*, 153 F.2d 428 (2nd Cir. 1946).”

In sharp contrast, to *Adams Battery*, dictum in *Mayo* suggests that the claims may be parsed to focus on an individual element to determine patent-eligibility. *Mayo* conflicts with precedent by dissecting a combination claim to consider whether each of the components, itself, is inventive or nonobvious, and not whether the *combination* of elements is or is not inventive or nonobvious. The dissection of elements of the claimed invention in *Mayo* is instructive of the flawed Supreme Court reasoning:

What else is there in the claims before us [beyond the natural phenomenon]? The process that each claim recites tells doctors interested in the subject about the correlations that the researchers discovered. In doing so, it recites an "administering" step, a "determining" step, and a "wherein" step. These additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim.

[T]o consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. See *Diehr, supra*, at 188 ("[A] new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made"). Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.

The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; *any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately*. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

* * *

[T]he claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law. *These instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field.* And since they are steps that must be taken in order to apply the laws in question, the effect is simply to tell doctors to apply the law somehow when treating their patients. ***

Mayo, __ U.S. at __ (emphasis supplied; citations omitted).

C. Research “Preemption” as Basis to Deny Patent-Eligibility

1. “Preemption” is not Required per *Ariosa*

Is “preemption” of future research based upon the grant of a patent where *one element* under *Mayo* is to a “fundamental” principle basis to ignore “preemption” as a necessary and proper basis to deny patent-eligibility under Section 101?

The stated question in the introduction is an issue raised in the majority opinion in *Ariosa*: “The Supreme Court has made clear that the principle of preemption is the basis for the judicial exceptions to patentability. *** For this reason, questions on preemption are inherent in and resolved by the § 101 analysis. The concern is that “patent law not inhibit further discovery by improperly tying up the future use of these building blocks of human ingenuity.” *Id.* (internal quotations omitted). In other words, patent claims should not prevent the use of the basic building blocks of technology—abstract ideas, naturally occurring phenomena, and natural laws.” See § III, C, *Deuterium Ghost at the Federal Circuit* (quoting *Ariosa*, __ F.3d at __ (Reyna, J.)(citation deleted). The majority opinion concludes that “[w]here a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework *** preemption concerns are fully addressed and made moot.” *Ariosa*, __ F.3d at __ (Reyna, J.).

2. The Fundamental Issue of “Research Preemption”

Because of the fact that the DNA present in one element of the claimed process in *Ariosa* is neither claimed, per se, nor is a use of that DNA claimed, it is clear that there is absolutely no “preemption” of the use of that DNA for future research.

It is thus unnecessary to answer the more fundamental question as to whether the grant of a claim to *any* subject matter “preempts” follow-on research, an issue in dispute within the Federal Circuit due to the aberrant *Deuterium* line of case law within that body that has never been repudiated by the *en banc* court. See § IV-C, *Deuterium Ghost at the Federal Circuit* (discussing *Deuterium Corp. v. United States*, 19 Cl.Ct. 624 (Cl.Ct.1990)(Rader, J.); *Embrex v. Service Eng'g Corp.*, 216 F.3d 1343 (Fed.Cir.2000) (Rader, J., concurring); *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed.Cir.2002)(Gajarsa, J.)).

3. The Preemption Argument in *Ariosa* is Absurd

Only with a rigid reading of *Mayo* and *Alice* can one come to the conclusion that the invention in *Ariosa* lacks patent-eligibility. The rigid test set forth in *Alice* states that:

[T]he preemption concern [] undergirds our §101 jurisprudence. Given the ubiquity of computers, see 717 F.3d [1269, 1286 (Fed. Cir. 2013)] (Lourie, J., concurring), wholly generic computer implementation is not generally the sort of ‘additional featur[e]’ that provides any ‘practical assurance that the process is more than a drafting effort designed to monopolize the [abstract idea] itself.’ [quoting *Mayo*]

The fact that a computer ‘necessarily exist[s] in the physical, rather than purely conceptual, realm,’ Brief for Petitioner 39, is beside the point. There is no dispute that a computer is a tangible system (in §101 terms, a ‘machine’), or that many computer-implemented claims are formally addressed to patent-eligible subject matter. But if that were the end of the §101 inquiry, an applicant could claim any principle of the physical or social sciences by reciting a computer system configured to implement the relevant concept. Such a result would make the determination of patent eligibility ‘depend simply on the draftsman’s art,’ [*Parker v. Flook*, 437 U.S. 584, 593 (1978),] thereby eviscerating the rule that ‘[l]aws of nature, natural phenomena, and abstract ideas are not patentable,’ [quoting *Myriad*]

But, the invention *as claimed* in *Alice* provides absolutely no preemption of the DNA involved in the claimed invention. There is no more preemption of the use of that DNA in the future as that very DNA of the claimed invention is *neither* claimed *nor* is a use of the DNA claimed: The DNA is merely *identified* in the claimed invention. To say that the claim in *Ariosa* “preempts” the use of the DNA would be akin to saying that identification of a biological sample under a

microscope is “preempted” for future use, merely because the method of identification is patented. For example, if identifying a particular biological sample required a unique *staining* of that sample before inspection under the microscope, if nonobvious, one could obtain the method of identifying the biological sample by first staining the sample prior to evaluation under the microscope.

What *Ariosa* teaches is that the rigid model of *Mayo* and *Alice* does not present a one-size-fits-all answer to determination whether an invention is or is not patent-eligible.



IX. SHOULD *ARIOS*A BE REHEARD *EN BANC*?

A. *Sua Sponte* Consideration of Issues within the *Arios*a Opinion

The court has the authority to *sua sponte* order rehearing *en banc* without the petition of a party. There are two pressing issues where, indeed, it would be reasonable to grant rehearing *en banc*:

Is there subject matter that is “inventive” – nonobvious under 35 USC § 103 – that somehow lacks patent-eligibility under 35 USC § 101? *See* § IX-A-1, *Arios*a Breaks the *Mayo* Patent-Eligibility Mold.

Should the presence of “inventive” subject matter be based upon “all elements” of the claimed subject matter consistent with nineteenth century foundational “all elements” case law or may the presence of an “abstract” or other section 101 subject matter as an *element* of the claimed invention be basis to deny patent-eligibility of the invention as claimed? *See* § IX-B, *Patent-Eligibility Keyed to the Invention As a Whole*.

To the extent that the court can create a consensus position on either of the above issues it certainly would be an important contribution for the court to grant rehearing *en banc*. A note of caution is in order:

Is there a *realistic* chance that a consensus – or at least an overwhelming majority – can be garnered at the Federal Circuit for a resolution of either issue? To the extent that the court is hopelessly split on either issue, it does no good for the court to grant *en banc* review simply to publicize its existing split. As in cases such as *Bilski* an *en banc* exposition of a hopelessly divided Federal Circuit merely advertises the split to patent community and creates a *carte blanche* invitation to the Supreme Court to grant *certiorari* review.

B. Should the Petition for *En Banc* Review in *Ariosa* be Granted

The patentee-petitioner challenges the *Ariosa* decision because “this case is contrary to *Diamond v. Diehr*, 450 U.S. 175 (1981), *Mayo v. Prometheus Laboratories*, 132 S. Ct. 1289 (2012), and *Association for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013)[.]” All three of *Ariosa*, *Mayo* and *Myriad* have the same *holdings* of a denial of patent-eligibility, while the conflicting *Diehr* case is distinguished in *Mayo* and *Myriad*.

To be sure, one may see a conflict amongst the 1981 *Diehr* case finding patent-eligibility in the very recent *Mayo* and *Myriad* cases which deny patent-eligibility. Whatever conflict there has been between the two recent cases and the much earlier *Diehr* has been resolved by the Court itself in *Mayo* and *Myriad* by their actions distinguishing *Diehr*.

Wegner, *Patent Eligibility*

The question then is whether under FRAP 35(b)(1)(A) whether there is a conflict between the holding of the *Ariosa* panel opinion and the holdings of *Mayo* and *Myriad*. (See FRAP 35(b)(1)(A), requiring that “[t]he petition must begin with a statement that *** the panel decision *conflicts* with a decision of the United States Supreme Court ****.”)

The answer is a simple “no”, the petition should be denied as to the issue presented: There is simply no conflict between the *holdings* of *Mayo*, *Myriad* and *Ariosa*. In all three cases patent-eligibility was denied.



X. PTO PATENT-ELIGIBILITY EXAMINATION GUIDANCE

A. What the PTO Should Do

The Patent Office in its guidance to examiners for *ex parte* prosecution of patent applications where there is an issue of patent-eligibility should be held to two strict rules for examination:

Rule One: “Inventive” subject matter should be judged based upon whether the subject matter meets the statutory test of nonobviousness under 35 USC § 103 which superseded the *Hotchkiss* case law standard.

Rule Two: The presence of “inventive” subject matter should be based upon the claimed invention under the “all elements” rule which whereby “inventive” subject matter is based upon the claimed invention *as a whole* including all of its elements, and *not* based upon whether one of the elements, standing alone, may lack patent-eligibility.

B. PTO Abdication of its Basic Examination Function

Whether the issue is Section 101 patent-eligibility or Section 103 nonobviousness a fundamental function of the Examiner is to *search* to determine whether claimed subject matter is “inventive” or has an “inventive concept” under the pre-1952 case law or nonobvious under the statutory test of 35 USC § 103. It is thus the fundamental task of the examiner for the roughly 180 years since the creation of the modern Patent Office to *search* the prior art and then – since the mid-nineteenth century under *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1850) – come forward with a determination whether claimed subject matter is “inventive” or “nonobvious”.

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There is no escaping this fundamental task, whether the inquiry is under the traditional test of nonobviousness under Section 103 or whether the task is to make out a *prima facie* case of lack of an “inventive” feature under Section 101. Yet, the current guidance of the Office tells the examining corps to do essentially everything *but* an analysis for “inventive” features or “nonobviousness”, whichever label is chosen:

“The abstract idea exception, like the other judicial exceptions, was created by the courts to protect the building blocks of ingenuity, scientific exploration, technological work, and the modern economy. Because the courts have declined to define abstract ideas, other than by example, the [original 2014 guidance] instructs examiners to refer to the body of case law precedent in order to identify abstract ideas by way of comparison to concepts already found to be abstract. Accordingly, the following discussion provides more information about the types of concepts the courts have considered to be abstract ideas, by associating Supreme Court and Federal Circuit eligibility decisions with judicial descriptors (*e.g.*, ‘certain methods of organizing human activities’) based on common characteristics. These associations define the judicial descriptors in a manner that stays within the confines of the judicial precedent, with the understanding that these associations are not mutually exclusive, *i.e.*, some concepts may be associated with more than one judicial descriptor. This discussion is meant to guide examiners and ensure that a claimed concept is not identified as an abstract idea unless it is similar to at least one concept that the courts have identified as an abstract idea.

“When identifying abstract ideas, examiners should keep in mind that judicial exceptions need not be old or long-prevalent, and that even newly discovered judicial exceptions are still exceptions, despite their novelty. For example, the mathematical formula in *Flook*, the laws of nature in *Mayo*, and the isolated DNA in *Myriad* were all novel, but nonetheless were considered by the Supreme Court to be judicial exceptions because they were “‘basic tools of scientific and technological work’ that lie beyond the domain of patent protection.” The Supreme Court’s cited rationale for considering even ‘just discovered’ judicial exceptions as exceptions stems from the concern that ‘without this exception, there would be considerable danger that the grant of patents would ‘tie up’ the use of such tools

and thereby ‘inhibit future innovation premised upon them.’” The Federal Circuit has also applied this principle, for example, when holding the concept of using advertising as an exchange or currency abstract in *Ultramercial*, despite the patentee’s arguments that the concept was ‘new’.”

July 2015 Update: Subject Matter Eligibility, available under 2014 Interim Guidance on Subject Matter Eligibility (July 30, 2015), § III, *Further Information on Identifying Abstract Ideas in Step 2A*, p. 3 (footnotes omitted) available at <http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0> at <http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0>.

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That the Examiner is *not* required to search and examine for an “inventive” feature is bluntly explained by the Office in its most recent guidance:

“The concept of the *prima facie* case is a procedural tool of patent examination, which allocates the burdens going forward between the examiner and applicant. In particular, the initial burden is on the examiner to explain why a claim or claims are unpatentable clearly and specifically, so that applicant has sufficient notice and is able to effectively respond. For subject matter eligibility, *the examiner’s burden is met by clearly articulating the reason(s) why the claimed invention is not eligible, for example by providing a reasoned rationale that identifies the judicial exception recited in the claim and why it is considered an exception, and that identifies the additional elements in the claim (if any) and explains why they do not amount to significantly more than the exception.* This rationale may rely, where appropriate, on the knowledge generally available to those in the art, on the case law precedent, on applicant’s own disclosure, or on evidence.”

Id. at § IV, *Requirements of a Prima Facie Case*, p. 7 (emphasis added; footnotes omitted).

C. Opportunity to Raise a Standalone Section 101 Issue

It must be recognized that there is current split within the Federal Circuit whether there is basis for determination that “inventive” subject matter may nevertheless be denied patent-eligibility because the subject matter lacks a “significant ‘inventive concept.’” *CLS Bank Int’l v. Alice Corp.*, 717 F.3d 1269, 1291 (Fed. Cir. 2013)(en banc)(Lourie, J., joined by Dyk, Prost, Reyna, Wallach, JJ., concurring)(quoting *dicta* in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012)), *subsequent proceedings, Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014).

Unless this split is resolved with a determination that “inventive” and nonobvious subject matter have congruent scope, there must be an opportunity to raise the issue at the Patent Office. But, even if the test of a “significant ‘inventive concept’” is the outcome of a resolution of this intra-circuit split, the opportunities for an *ex parte* examination to consider the issue should be limited.

To be sure, even if an Examiner in *ex parte* procurement is required to reach a conclusion as to an “inventive” feature based upon nonobviousness, there is nothing to preclude the public from raising a challenge under Section 101 in a Post Grant Review.

D. Honoring Supreme Court Rules for Patent Litigation

The Supreme Court in its evaluation of patent-eligibility declined the Government's suggestion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012), to focus a validity determination on patentability issues under 35 USC §§ 102, 103, 112:

[T]he Government argues that virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy §101's demands. Brief for United States as *Amicus Curiae*. The Government does not necessarily believe that claims that (like the claims before us) extend just minimally beyond a law of nature should receive patents. But in its view, 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. In particular, it argues that these claims likely fail for lack of novelty under §102.

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. [citing *Bilski*; *Diehr*; *Flook*; *Benson*] See also H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952) (‘A person may have ‘invented’ a machine or a manufacture, which may include anything under the sun that is made by man, *but it is not necessarily patentable under section 101* unless the conditions of the title are fulfilled’ (emphasis added)).

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.

Mayo v. Prometheus, 132 S.Ct. at ____.

But, there is no requirement in *Mayo* that trumps the obligation of the Patent Office to require consideration of an “inventive” feature without first considering whether the invention is nonobvious and thus has an inventive feature.

E. “Markedly Different Characteristics” Guidance

Under Secretary Michelle K. Lee has issued updated guidance on patent eligibility in her *July 2015 Update: Subject Matter Eligibility*, available under 2014 Interim Guidance on Subject Matter Eligibility (July 30, 2015), available at <http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0> at <http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0>.

Included is a section that borrows from *dictum* in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), and more recent cases. She concludes that:

“[A Markedly Different Characteristics (MDC)] analysis ... allows many claims to qualify as eligible early in the analysis, *i.e.*, as soon as it is determined that no ‘product of nature’ is recited in the claim. For instance, ... once it is determined that the recited nature-based product has [markedly different characteristics] from what occurs in nature, the claim qualifies as eligible subject matter. This early eligibility mirrors how the claims in *Chakrabarty* and *Myriad* (with respect to cDNA) were held eligible ... after the Supreme Court determined that no ‘product of nature’ was recited in the claims at issue.”

Id. at § II, *Further Explanation of the Markedly Different Characteristics Analysis*, pp. 2-3.

Wegner, *Patent Eligibility*

The quoted guidance manifests an unfamiliarity with *Chakrabarty*. As explained elsewhere, it was a *given* that the subject matter in *Chakrabarty* is “inventive” and indeed has a higher standard of invention than the bare minimum; more importantly, the statement is *dictum* unnecessary to the holding in the case. See § VII-A, “*Inventive*”, *Nonobvious Subject Matter without Question*.



X. CONCLUSION

The direction of future patent-supported research in the critical areas of biotechnology and pharmaceutical as well as software is uncertain, given the unprecedented deviation from the historic open-door to patent-eligibility that is the result of the 1623-1624 Statute of Monopolies.

Developments in the coming years will help determine whether patent-supported research efforts will continue to stimulate the Progress of the Useful Arts in these important, cutting edge areas of technology.



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Prof. Wegner is available to cooperate with corporate and law firm colleagues on matters involving patent drafting and procurement strategies, appellate matters, opinions and expert testimony.

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Professor Wegner is a former Patent Examiner who recently concluded a more than twenty year relationship with the George Washington University Law School where he had been Director of the Intellectual Property Law Program and Professor of Law.

Professor Wegner operates as an independent consultant following his retirement from Foley & Lardner LLP following twenty years with the firm.

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