THE *SEQUENOM* **PATENT ELIGIBILITY CHALLENGE***

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SUMMARY OF CONTENTS

CRAFTING A SUCCESSFUL PATENT APPLICATION

While it is an open question what policies a new Administration that takes Office in 2017 may have concerning patent-eligibility, the *current* picture under the incumbent Under Secretary in charge of the Patent Office is bleak. The focal point, *here*, is to provide a basis to establish patent-eligibility *at the Patent Trial and Appeal Board* and, if necessary, at the Federal Circuit.

Until such time as the Supreme Court, "tomorrow", revises its current, bleak case law on patent-eligibility, guidance is provided for how to draft and prosecute an application "today" in the following sections:

RELATIONSHIP TO FIRST-TO-FILE PATENT DRAFTING

The present monograph deals with the shifting sands of the case law relating to patent-eligibility under 35 USC § 101, particularly software-implemented innovations that include an "abstract" element and claims to methods and products keyed to an "element" that involves a principle of "nature"

The present monograph is designed to be used as a *supplement* to the primary text, FIRST-TO-FILE PATENT DRAFTING, which provides a simplified method to prepare a better patent application in a more efficient manner as explained in the preface to that book, reproduced below, as *Preface to* FIRST-TO-FILE PATENT DRAFTING Monograph.

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PREFACE TO THE *FIRST TO FILE PATENT DRAFTING* MONOGRAPH

This book takes a front end view of the patent process: The vantage point is the preparation for the very *first* filing, which usually will be either a domestic provisional or an overseas Paris Convention application. This first filing, accomplished "today", will serve as a priority base for a second filing a year later as a regular (non-provisional) application. That second filing will be examined "tomorrow", perhaps in 2018 or later under a new Administration. Many changes may take place between "today" and "tomorrow", both in terms of the trend of the case law as well as examination policies of a new Under Secretary of Commerce. The biggest possible change could occur in the area of patent-eligibility under 35 USC § 101 based upon the view of the new Administration toward patents. Thus, the focus of the drafting process in changing areas is to provide a specification that has flexibility to introduce new claim forms "tomorrow" that will find support in the filing "today". *See* § 1[b][7], *New Approach in a New Administration in 2017* (discussing options open under a more patent-friendly Under Secretary of Commerce).

A Three-Fold Approach to Patent Drafting

Three critical features are focal points: First, the patent drafting framework, here, is that of a *first*, priority application in a first-to-file world; *second*, a *business* approach is taken to the drafting process which determines whether the exercise process takes one hour or hundreds of hours; and *third*, a holistic, simple application is the goal, to present a patent document easy to understand for both an examiner and the courts, one that optimizes protection and minimizes technical pitfalls.

(1) The First, Priority Application in a First-to-File World

This book is about drafting the first *priority* application for a first-to-file world "today" for an application that will be examined "tomorrow" under a new Administration. *See* § 1[b][7], *New Approach in a New Administration in 2017* (discussing options open under a more patent-friendly Under Secretary of Commerce).

Over fifty percent of *all* United States patents have at least one and often several priorities keyed to a provisional or Paris Convention overseas priority application, or are daughter continuation, continuation-in-part or divisional applications. A time efficient drafting of the priority application is vitally important when facing the realities of a first-to-file patent regime where the grace period can *never* be part of a prospective drafting strategy. It does no good to file a "perfect" application with all the bells and whistles suggested by the *Manual of Patent Examining Procedure* when that application is filed the day after a junior inventor has filed a focused application keyed to the *essential* statutory elements necessary for a solid patent:

The race to the Patent Office must be won; there is no silver medal for coming in second. Or, where an invention is presented at a scientific conference with the idea that an application would be filed in the near future under the "grace period" when a member of the audience makes a prior art divulgation of a *variant* of the invention that is outside the scope of the grace period.

(2) A Business Manager's Perspective of the Drafting Process

Priority patent drafting is approached through the lens of a *business manager* without which the filing process makes no sense. Management needs to take a hands on approach to directing the drafting effort. The entire effort may take a matter of an hour or so or up to several hundred hours, depending upon the technology and the state of the innovation: Once given a complete technical description and drawings for the preferred embodiment, the *business objectives* for many filings may call for spending no more than an hour or so for an already *completed* invention filed for defensive purposes. (The harm in spending several hundred unnecessary hours on an application goes beyond the expense of drafting the application but may be fatal to all patent rights if the extra expenditure of time means that a true first inventor is second-to-file in a first-to-file world.) At the other end of the spectrum where an upstream prototype in an unpredictable technology has been visualized but the ultimate commercial embodiment is yet to be created, the drafting process may take hundreds of hours to provide working and prophetic exemplary support to complement broad generic claims.

(3) A Simple, Holistic Approach to Patent Drafting

An overarching goal is the presentation of a holistic document that is *simple*, an easy to understand application and one that is easy to examine. The patent applicant *may* present twenty or fifty or sixty claims in an application as a matter of right. The patent applicant *may* cite seventy or eighty prior art citations to meet his duty of disclosure. The patent applicant *may* present a detailed *Background of the Invention* reciting a multitude of problems faced by the inventor which he has overcome through his new invention. This approach while open as a matter of *right* to any inventor is at the same time a prescription for failure, a road to a protracted prosecution where the examiner is choked in a sea of too much information to digest within the limited time available for examination of each application.

Instead, each claim should be tied to a business objective: Many if not most applications should have five or ten or perhaps twelve or fifteen claims, and not the twenty or fifty of sixty claims. Where a prior art search has provided seventy or eighty citations, even if it is difficult to decide *which one* is the most pertinent, certainly a triage exercise can eliminate all but five or six prior art references as "cumulative": Eliminating most of the chaff makes the examiner's task much easier, which should be a goal of any presentation of a new application.

"Abstract" Software and "Natural" Product § 101 Patent-Eligibility

For a "how to" approach to draft claims today with the goal of piggybacking off the results of test cases that are sure to come in the coming months and years, reference is made to § 1[b], *Technology-Specific Patent-Eligibility Challenges.* An outline of how to draft a patent application "today" for inventions involving issues under Section 101 relating to patent-eligibility is contained in the §§ 1[b][1] – 1[b][3].

A far more detailed exposition of the legal issues is found in Chapter 15, *Claiming Patent-Eligible Subject Matter.*

An even more detailed exposition of the issues is found in a parallel monograph by this author, SEQUENOM PATENT-ELIGIBILITY CHALLENGE, which is designed for in depth study of the issues for the purpose of a test case at either the Patent Trial and Appeal Board or the Federal Circuit.

A Comparative Approach

The comparative material relating to Japanese patent law and practice is in large measure the result of the education given this writer by several persons including Tomatsu Aoyama, Shoichi Okuyama and Eiji Katayama. (It was Mr. Aoyama, together with Shoji Matsui and the late Professor Dr. Zentaro Kitagawa, who arranged the writer's early visits to Japan.) Thanks also are owed to Tetsu Tanabe for collaborations while the writer was a *Wissenschaftlicher Mitarbeiter* at the Max Planck Institute.

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A Thank you to Former Colleagues

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§ 1. OVERVIEW

The patent community today largely blames the Supreme Court for what is perceived as an anti-patent approach in its recent case law denying patent-eligibility keyed to the theme that patents "preempt" basic concepts.

But, it is time to recognize that it is the Federal Circuit that has upset the preemption case law applecart with its dangerous *Deuterium* line of case law. *See* § 3, *Alice Mythology of a Research "Preemption."* The court has drifted away from longstanding practice stemming from the early nineteenth century writings of Joseph Story that established the right to experiment on a patented invention. To be sure, there are mixed views within the Federal Circuit, but that court has failed to remove this incorrect viewpoint through an *en banc* exorcism. The court thus plays a significant, contributing role to the current "preemption" line of case law denials of patent-eligibility.

This monograph takes two different approaches to a study of patent-eligibility. The first deals with how test cases can be shaped to modify the law, PART (I) *Sequenom: Modifying the Case Law.*

The second offers a "Top Ten" list of ways to draft patent applications today to anticipate the evolution of the case law, PART (II) *Top Ten Patent Eligibility Drafting Rules.*

PART (I) *SEQUENOM*: MODIFYING THE CASE LAW

Of paramount importance in the shaping of the patent-eligibility case law is "*Sequenom v. Ariosa Diagnostics*", the likely styling of an early 2016 petition for *certiorari* to review the denial of patent-eligibility under 35 USC § 101 in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,788 F.3d 1371 (Fed. Cir. 2015)(Reyna, J.).

Sequenom is a center stage attraction in the patent community following the December 2, 2015, Federal Circuit denial of *en banc* review in *Ariosa.* The push for *certiorari* is fueled by plural opinions either concurring with the denial of *en banc* review or dissenting from such denial.

Sequenom has the potential to be the most important Supreme Court patent-eligibility case since the 2010 *Bilski* start of the current wave of denials of patent-eligibility. Will petitioner gain *certiorari*? If so, will he win the appeal? Until the

petition itself is filed it is impossible to accurately predict the outcome, particularly as it is the Petitioner who *defines* the issue in its "Question Presented".

A multitude of approaches can be taken. But, if all the approaches are taken and multiple "Questions Presented" are brought forward, this may well doom the chance for grant of *certiorari*. If Petitioner presents just one issue (and possibly two), then *how* an issue is presented may be critical to the Court granting review.

The Sequenom Invention does *not* Preempt Research

The recent *Bilski* line of case law has focused upon the Court's perceived need to avoid granting broad claims that "preempt" future research or use of abstract principles or claims that are based upon nature's "secrets." The theoretical foundation of the *Bilski* line of case law concerning the "secrets" of nature may be traced to the writing of the late William O. Douglas in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). The basic concept of the *Bilski* line of case law is that an abstract principle or "secret" of nature should not be basis for a patent grant that would thwart the Progress of the Useful Arts by blocking use of that abstract principle or "secret" of nature.

The Sequenom claimed invention requires (a) performing a test on "maternal serum or plasma sample" which has only a minor amount of paternal fetal DNA; (b) amplifying the DNA to permit testing; and (c) detecting the presence of paternally inherited nucleic acid. (Claim 1 is reproduced at the beginning of § 4, *Patent-Eligibility of the Claimed Invention.*) Thus, the claimed process involves DNA, but absolutely no preemption of the use of the "secrets" of nature. If the DNA involved in *Sequenom* at one time *was* a "secret" of nature, by the time of the invention the DNA under study was well known.

The invention is focused on *identification* of *known* DNA with *known* properties; no claim preempts *any* use of DNA because the DNA is neither *claimed* nor is any use of the DNA *claimed.*

In a nutshell the invention uses a simple blood sample drawn from a pregnant mother's arm for the pre-natal genetic test, whereas the previous genetic test requires a fetus-invasive drawing of amniotic fluid sample from the womb itself. The entire object of the claimed invention is to determine whether or not particular DNA is part of the genetic makeup of the fetus. In a way, one could draw an analogy to a "microscope" that is used to identify aspects of a biological sample where a powerful microscope is complemented by *staining* the biological

sample. In both *Sequenom* and the "microscope" example, the biological material is only a passive object of identification.

The Sequenom claimed subject matter is clearly "inventive" (which is beyond question). To be sure, part of the claimed subject matter involved *amplification* of the amount of prenatal DNA in the blood sample, which is accomplished through the polymerase chain reaction (PCR) technology which won a Nobel Prize in 1983 – fourteen years before the Sequenom invention.

The Various Section 101 Technology Issues

Section 101 patent-*eligibility* of "compositions" and "manufactures" as well as software "process" inventions are the focus of this monograph, particularly, the judicial *exceptions* to patent-eligibility in these categories such as the "abstract" elements of software innovations as well as patent-eligibility denial for innovations in the fields of biotechnology and pharmaceuticals. The *Sequenom* petition is the immediate 800 pound gorilla in the room: It has the potential to determine whether the downward patent-eligibility spiral will continue a fifteen year trend that started with *Bilski v. Kappos*, 561 U.S. 593 (2010), following thirty-five (35) years of peace in the patent-eligibility valley following *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). *Chakrabarty* came in the immediate wake of the most notorious denial of patent-eligibility of that era, *Parker* v. *Flook*, 437 U.S. 584 (1978).

In the interval between *Chakrabarty* and *Bilski* the Court granted *certiorari* review of patent-eligibility only twice; in both *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), challenges to patent-eligibility were denied. The steady denial of *certiorari* challenges abruptly ended with the internal disharmony at the Federal Circuit in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008)(en banc)(Michel, C.J.), that spawned the 2010 *Bilski v. Kappos.*

Will *Sequenom* be the same sort of "brake" on the fifteen year trend that started with *Bilski*, much as *Chakrabarty* put an end to the patent-eligibility bleeding just eight years after *Gottschalk v. Benson*, 409 U.S. 63 (1972), had started the first departure from patent-eligibility?

It is unknown at this time what issues will be presented to the Court in the *Sequenom* case, as it is up to the petitioner (and would be appellant) to define the issue as a *Question Presented.* The issues that *may* be raised and a more detailed preview of what's next at the Supreme Court is found in Chapter 9, *The Sequenom*

Petition for Certiorari which contains both excerpts from the three opinions as well as analysis.

In order to fully understand the issues that may be before the Supreme Court, it is preferable to start at the beginning, to see the evolution of the case law that first considered the issues in the nineteenth century. To avoid tunnel vision, and to take a macroscopic view of how the case should be presented, it is best to hold off reading the current controversies detailed in Chapter 9 until first reading the earlier chapters on the evolution of various doctrines.

The United States law of patent-eligibility, today, continues in a state of chaos that seemingly is without end. Starting with *Bilski* in 2010, the past fifteen years have seen repeated Supreme Court denials of patent-eligibility under 35 USC § 101 including *Mayo Collaborative 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 most recently *Alice Corporation Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014).

But, if past is prologue, we may very well be on verge of a reversal, just as occurred following a bleak anti-eligibility period starting with *Gottschalk* v. *Benson*, 409 U.S. 63 (1972); and continuing through *Parker* v. *Flook*, 437 U.S. 584 (1978): But, the pendulum swung back to the historical common understanding of patent-eligibility with *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); and *Diamond* v. *Diehr*, 450 U.S. 175 (1981); *Chakrabarty* started a thirty year period of Supreme Court pro-eligibility case law.

This monograph is in the end intended to provide a positive message as to how to *successfully* draft and prosecute a patent application to a novel product which involves an element which is "abstract" derived from a "product of nature", to gain protection where the element, standing alone, lacks patent-eligibility under 35 USC § 101.

Patent Eligibility *Stare Decisis*

The starting point for a reconsideration of the patent-eligibility case law is to study the foundational decisions from the nineteenth century which are contemporaneously characterized as standing for principles relating to patent-eligibility when in fact they generally have nothing to do with this issue. *Amici* who start their arguments by reiterating contemporaneous characterizations of foundational case law are the antithesis of being friends of the court.

Recent Supreme Court and Federal Circuit cases have uncritically stated that the current judicial exceptions to patent-eligibility may be traced back "150 years" to English precedent from the early nineteenth century and mid-nineteenth century American cases; this is pure nonsense. *See* § 2, *"150 Years" Of Patent-Eligibility Stare Decisis* (discussing *Household 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)).

As reiterated in *Alice*, 134 S. Ct. at 2354 (quoting the *Myriad* case, 133 S.Ct. at 2116), the Court says 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.' " *See also* § 2[a][1], *Early English Household Coal Case*; § 2[a][2], *Le Roy v. Tatham, The Lead Pipe Case.*

The Federal Circuit has perpetuated the mythology through its statements, for example, of "*stare decisis* going back 150 years" denying patent-eligibility. *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.) at 174-75), *subsequent proceedings sub nom Mayo v. Prometheus Laboratories, supra.*

A second Federal Circuit panel announced that "[p]rohibitions 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).

The inaccuracy of the summaries of *Household Coal*, *Le Roy v. Tatham*, *O'Reilly v. Morse* and the *Rubber-Tipped Pencil* cases is explained with precision by Professor Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. 565, 594-96 (2015); *see also* Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence of Abstractions*, 16 N. C. J. L. & Tech. 647, 666-67 (2015)(discussing *O'Reilly v. Morse*). Persons relying upon *O'Reilly* v. *Morse* as denying patent-eligibility have often done so *without* noting that most of the claims of the Morse patent were *upheld*, as explained by Professor 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.

Fifteen Years under *Bilski*

For anyone who started patent practice since 2010 there has been an unbroken string of Supreme Court cases where patent-eligibility has been denied, from *Bilski* to *Alice*; sandwiched within this period are *Mayo v. Prometheus* and *Myriad*.

The current fifteen year period – still ongoing – is the longest stretch in the history of the United States where patent applicants and patentees have either been denied patent rights or lost them on the basis of a lack of *holdings* of patent-eligibility.

The Eight Year *Benson-Flook* Period of Instability

This is not the first time in the modern era that we have experienced a patent-eligibility crisis. For less than one full decade we had the same problem starting with the 1972 *Benson* case that ended only with the 1980 *Chakrabarty* case (enhanced by the 1981 *Diehr* case) that ushered in a rational treatment of patent-eligibility that lasted for almost three full decades up until *Bilski*. Until *Bilski*, *certiorari* to consider patent-eligibility was granted in only one case, *J.E.M. Ag Supply, Inc. v Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001)(seed patent-eligibility), and in that case the Court reaffirmed its adherence to *Chakrabarty* and *Diehr*.

The "*Mayo*/*Alice* framework" in *Sequenom*

The Federal Circuit speaks of a very difficult anti-patentee regime that has been styled as the *Mayo*/*Alice* framework. *See* § 4[c], *The Alice Restatement of Mayo Patent-Eligibility Exclusions* (discussing *Mayo v. Prometheus* and *Alice Corp. v. CLS Bank*)).

The *Mayo/Alice* analysis asks whether there is "an ordered combination" that has an "inventive concept", the presence of which puts the subject matter in the category of patent-eligibility under 35 USC § 101. *DDR Holdings, LLC v. Hotels.Com, L.P.*, 773 F.3d 1245, 1255 (Fed. Cir. 2014)(Chen, J.). Citing *Alice*, 134 S.Ct. at 2355, the court "determine[s] whether the claims at issue are directed to a patent-ineligible abstract idea. If so, we then 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 of that abstract idea. *Id.* This second step is the search for an "inventive concept," or some element or *combination of elements* sufficient to ensure that the claim in practice amounts to "significantly more" than a patent on an ineligible

concept. *Id." DDR Holdings*, 773 F.3d at 1255 (emphasis added). *See also Content Extraction and Transmission LLC v. Wells Fargo Bank*, 776 F.3d 1343, 1346-47 (Fed. Cir., 2014)(Chen, J.)("The Supreme Court's two-step framework, described in *Mayo* and *Alice*, guides our analysis. *Alice* [*Corp. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2355 (2014)] (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1296–97 (2012)). We first determine whether a claim is 'directed to' a patent-ineligible abstract idea. If so, we then consider the elements of the claim—both individually and *as an ordered combination* —to assess whether the additional elements transform the nature of the claim into a patent-eligible application of the abstract idea. *Id.* This is the search for an 'inventive concept'—something sufficient to ensure that the claim amounts to 'significantly more' than the abstract idea itself. *Id.*"(emphasis added).

The gist of the *Mayo/Alice* analytical framework is that if there is an "ordered combination" that is "inventive" then the grant of a patent to such an inventive, "ordered combination" does not in any way preempt the public from using the underlying otherwise patent-ineligible basic tool for research.

What makes the *Sequenom* case particularly bizarre is that the patentee does not claim to have discovered a new biotechnology entity nor any new use for a well known biotechnology entity. He has merely discovered a way to *identify* particular, known DNA within a bodily fluid sample that has absolutely nothing to do with "preemption" of any kind nor, in the words of Justice Douglas, unearthing one of "nature's secrets." *See Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948)("The application of [a] newly-discovered natural principle *** may well have been an important commercial advance. But once *nature's secret* ***was discovered, the state of the art made the production of a mixed inoculant a simple step." *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948) (emphasis added). The Court concludes that "[t]here is no way in which we could call [the claimed subject matter the product of invention] unless we borrowed invention from the discovery of the natural principle itself. *** But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed." *Id.*

The stated Supreme Court public policy purpose for "preemption" from patent-eligibility is that without preemption "there would be considerable danger that the grant of patents would 'tie up' the use of such [basic research] tools and thereby 'inhibit future innovation premised upon them.'" *See* § 8[c][3], *The Preemption Argument in Ariosa is Mistaken* (quoting *Myriad*, 133 S.Ct. at 2013, quoting *Mayo v. Prometheus*, 132 S. Ct. at 1301).

The court in *Alice* explains that it is "preemption" of future innovation that is the basis for the exclusions to patent-eligibility under 35 USC §101. *See* § 4[c][1], *Morse Concern over "Preemption"* (discussing *Bilski,* 561 U.S. at 611-12 (2010), and *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 113 (1854)).

But, insofar as research preemption is concerned, patents as properly understood do *not* in any event preempt experimentation "on" a patented invention. *See* § 4[c][1][A], *Patents do not "Preempt" Research;* see also § 3, *Alice Mythology of a Research "Preemption". See,* particularly, Janice M. Mueller, *No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools,* 76 Wash. L.Rev. 1, 17 (2001).

A further concept in recent Supreme Court decisions is that "*too much* patent protection can impede rather than `promote the Progress of Science and useful Arts' which is also directly contrary to long-established case law where claims to pioneer inventions have been rewarded with a scope of protection *beyond* the literal wording of claims. *See* § 2[b][1], *"Too Much" Patent Protection vs. Real World Realities.*

Recent decisions – including *Alice* – have said that patent-eligibility stands where an otherwise ineligible feature, standing alone, is part of an "inventive" combination. *See* § 4[c][1][B], *An "Inventive" Application is Patent-Eligible.*

Merely because an element that alone lacks patent-eligibility is part of a claimed invention should not lead to denial of patent-eligibility of the claimed invention where that element is not itself protected either as a product or as to its use, and particularly not where the focus of a natural product invention is merely the *identification* of the product that preempts nobody from making or using that product. *See* § 4[c][1][C], *Identifying a Natural Product does not Preempt its Use.* This principle finds direct applicability in the *Sequenom* case where the patentee claims a method to *identify* DNA: The patentee claims neither DNA nor its use. *See* § 4[c][1][C], *Identifying a Natural Product does not Preempt its Use.*

Disregarding for the moment the existence of a researcher's right to experiment "on" a patented invention (as explained by Professor Janice M. Mueller, *supra*), and even stretching *Mayo* and *Alice* to the extreme that *any* even infinitely small amount of "preemption" of future research should not be tolerated, *there is absolutely no preemption of the use of any DNA of any kind for any purpose in the Sequenom patent.* Any DNA in the bodily fluid sample tested in the invention is not claimed – neither the bodily fluid nor any DNA contained in that fluid. Whatever DNA may be present in the tested bodily fluid is merely *amplified*

for testing purposes. Clearly, there is absolutely no "preemption" of the use of any DNA for any purpose.

The Return Swing of the Patent-Eligibility Pendulum

Will the patent-eligibility pendulum swing back toward the middle, toward a rational case law and policy along the lines of *Chakrabarty* and *Diehr*? Yes, at least to some extent, although the road today is more difficult than it was thirty years earlier at the time of *Chakrabarty* and *Diehr*. First of all, the blame for *Bilski* should not be placed upon what happened at the Supreme Court, but rather the chaotic evolution of the case law at the appellate court. Most glaring is the fact that unlike the decisions *affirming* broad patent-eligibility at the CCPA in the *Benson, Flook, Chakrabarty* and *Diehr* cases, today the successor Federal Circuit has created a case law quagmire where patent-eligibility was *denied* in the *en banc* decision in *Bilski.*

A more difficult case law regime exists today which at first blush supports denial of patent-eligibility and the incorrect view that patents "preempt" research and the remarkable conclusion in *Bilski* and progeny that "too much patent protection" stifles innovation. While a broad patent by definition may, *arguendo*, stifle *commercial competitors* of a patentee from practicing the patented invention, a patent does not block innovation because of the historic right to experiment "on" a patented invention, as explained by Professor Janice M. Mueller, *supra.* The right to experiment "on" a patented invention dates back to the early days of the country with pronouncements by legendary Justice Joseph Story such as *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) (Story, J.).

To be sure, the Federal Circuit has muddied the case law on experimental use to the point that it is necessary for an *en banc* review of its case law to clarify the continued viability of the *Whittemore v. Cutter* line of case law. *See* § 3[c], *Deuterium Ghost at the Federal Circuit* (discussing *Deuterium Corp. v. United States*, 19 Cl.Ct. 624 (1990)(Rader, J.)(denying the existence of a right to experiment on a patented invention by 'question[ing] whether any infringing use can be de minimis.'").

The *Bilski* Argument Against "Too Much Patent Protection"

The argument is made in recent Supreme Court case law that "too much patent protection" stifles commercial competition in the patented invention. Assuming, *arguendo*, the accuracy of that theory, commercial competition has nothing to do with the Constitutional foundation for the patent system which is not to deal with commercial competition but rather to *encourage innovation*, to "Promote the Progress of *** the Useful Arts." The Supreme Court in the nineteenth century furthermore supported broader protection for basic innovations: It was a question of providing *more* coverage, the antithesis of a world view that there should not be "too much patent protection." See § 2[b][1], "*Too Much" Patent Protection vs. Real World Realities* (discussing *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc*., 548 U.S. 124, 126 (2006) (Breyer, J., joined by Stevens, Souter, JJ., dissenting from dismissal of writ of certiorari)("[S]ometimes too much patent protection can impede rather than `promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection.") (emphasis in original); see also *Bilski v. Kappos*, 561 U. S. 593 (2010)(Stevens, J., joined by Ginsburg, Breyer, Sotomayor, concurring in the judgement); see also *In re Bilski*, 545 F.3d 943, 1006 (Fed. Cir. 2008)(en banc)(Mayer, J., dissenting), further proceedings sub nom *Bilski v. Kappos*, 561 U.S. 593 (2010).)

In fact, the premise that a broad claim is anti-competitive is also open to question as it is a rare event that a pioneer, patented invention provides a commercial monopoly on a particular field, as the subject matter of that broad claim starts with a zero market position in competition with long established and thriving technologies. The pioneer patentee often needs every break possible to crack into a new field. This was recognized in the early Supreme Court case law that allowed for a liberal doctrine of equivalents *beyond the scope of the claim* to protect the pioneer inventor, the antithesis of the contemporary argument that there may be "too much patent protection." *See* § 3[a][2], *Broad Patents "Promote the Progress of *** the Useful Arts; see also* § 2[b][2], *Early Supreme Court Recognition of the Need for Broad Protection* (citing *Morley Sewing-Machine Co. v. Lancaster*, 129 U. S. 263 (1889); *Miller v. Eagle Mfg. Co*., 151 U. S. 186 (1894); *Cimiotti Unhairing Co. v. American Fur Refining Co*., 198 U.S. 399 (1905); *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 (1908)).

PART (II): TOP TEN PATENT ELIGIBILITY DRAFTING RULES

Rule 1: Claims should be defined free from Patentability Issues

The first rule should be to determine whether the issue involved with the present invention actually *is* a patent-eligibility issue. There is so much confusion in nomenclature that often an invention that is denied on the basis of lack of patent-eligibility actually is *unpatentable* for one or more reasons.

Some of the patent-eligibility cases have, in fact, raised issues of *patentability* that were decisive in denying patentability or reaching a conclusion of invalidity. Most notoriously one may mention the "apply it" case law.

Rule 2: Claims should be Directed to Clearly Novel Subject Matter

The claims as drafted may be too close to the prior art, and in some cases the claims may actually read on an embodiment of the prior art, and hence lack novelty under 35 USC § 102. Here, it's back to the drawing boards to redraft claims that *define* a novel contribution.

Rule 3: Claims should be to "Inventive" (Non-Obvious) Subject Matter

The claims may define a novel contribution, but the claims as drafted cover subject matter at the periphery where that subject matter is *obvious* under 35 USC § 103. Again, it's back to the drawing boards.

Rule 4: A Combination Claim does not "Preempt" an Abstract Element

The claims may feature an element that, without more, lacks patent-eligibility. Here, claims must be drafted to a *combination* of elements where the combination is novel so that there is no "preemption" of the element, standing alone.

Rule 5: The Claimed Combination must be "Inventive"

Even if a combination claim is devised that combines an element lacking patent-eligibility with a second element, it is not enough that this combination is novel. Rather, a combination claim should be devised that is also to *nonobvious* subject matter under 35 USC § 103, i.e., the combination is "inventive". To be sure, there is case law that denies patent-eligibility under 35 USC § 101 where the combination claim is to obvious subject matter. But, what's the point in claiming subject matter that is rejected under Section 101 for lack of patent-eligibility when the claimed subject matter is in any event obvious under Section 103?

Rule 6: The Claimed Combination should be Sharply Defined

Where the applicant *does* present a claim to an inventive combination, it is important to present a specification that *defines* the invention as limited to the combination and not to evaluation of an individual element. The patentee has the right to be his own lexicographer and can include in his *Summary of the Invention* a statement that the invention consists entirely of the *claimed combination.*

Rule 6: Lack of Motivation to Make the Claimed Combination

The lack of *motivation* to combine the elements of the invention should be shown during prosecution. In hindsight it is too easy to simply say that "element A" and "feature B" can be combined like a jigsaw puzzle. The *Ariosa* factual pattern represents a text book case where there is no motivation shown in the prior art to put together the claimed combination of steps.

Rule 8: Recognition of a Problem without a Solution

The element that is either "abstract" or derived from a "product of nature" may have been well understood for many years, but there was nothing in the prior art that recognized the claimed *combination*.

Rule 9: Literature "Teaching Away" Manifests "Inventiveness"

Literature showing that the prior art *teaches away* from the claimed invention is a powerful tool to demonstrate that the combination is not in fact obvious.

Rule 10: The "2015 Lee Guidance" has Little Relevance

The notorious 2015 Lee Guidance should be largely ignored. If anything, it represents a confusing list of cases without analysis. While official guidance from the Patent Office on *procedural* issues within its domain is important, an interpretation of substantive patent case law by the Under Secretary is of at best minor importance vis a vis the actual case law itself. If anything at the Patent Office is important in dealing with case law, it is the decisional law of the Patent Trial and Appeal Board.

A Five-Fold Approach to Argumentation at the Patent Office

As explained in more detail at § 10[a], *A Five Step Proposal for Patent Eligibility Examination*, a proper case to establish patent-eligibility should involve five basic steps:

Step One: Without considering judicial exceptions to patent-eligibility, is the claimed subject matter any of a "new and useful process, *** manufacture, or composition of matter[.]"? If the answer is "yes", go to Step Two.

Step Two: If the answer to Step One is "yes", is there any implication of a "law of nature," "natural phenomenon," or "abstract idea" in any element of the claim? If the answer is "no", there is no issue of patent-eligibility. If the answer is "yes", go to Step Three.

Step Three: Determine the literal scope of the metes and bounds of the claim in question which defines the scope of the invention, following the "all elements" rule that requires looking at all stated elements as limitations.

Step Four: Is the claimed subject matter *as a whole* "inventive" within the meaning of the statutory test of nonobviousness under 35 USC § 103 (superseding the *Hotchkiss* case law standard).

Step Five: If the answer to Step Four is *affirmative*, then the claimed subject matter meets the patent-eligibility standard of 35 USC §101.

"Chakrabarty II", A Test Case to Refine Supreme Court Case Law

The road to a restoration of a proper balance and a renewed open door to patent-eligibility under 35 USC § 101 is not an easy task, and one where the balance in the end, however, must be restored: This monograph is all about patent-eligibility and how little by little it may be possible to restore the balance, to reopen the patent-eligibility door seemingly slammed shut in the recent period of Supreme Court denials of patent-eligibility.

As in 1980 with *Chakrabarty*, a proper test case must be selected as an appropriate vehicle. The choice of *Chakrabarty* as the test vehicle (as opposed to an appeal in its companion case, *In re Bergy*, 596 F.2d 952 (CCPA 1979) was critical).

The obstacles to reversing the negative trend of Supreme Court case law include in the first instance establishing a clear understanding of the difference between the noninfringing right to experiment "on" a patented invention, e.g., to see how a patented microscope works, as distinguished from an infringing experimentation "with" a patented invention, e.g., using a microscope for its intended purpose. *See* Janice M. Mueller, *No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L.Rev. 1 (2001). In the second instance, the Federal Circuit needs to remove the stain of *Deuterium* and other cases that deny the right to experiment

"on" a patented invention. *See* § 3[d], *Dueterium, a Fantasyland Solution to a Real Problem; see also* § 3[e], *Experimentation "On" Technology: The Industry Norm.*

Further complicating matters today is the fact that two of the more important voices of the *Chakrabarty* era are no longer around to help shape the contours of the case law, the late Howard T. Markey and the late Giles Sutherland Rich. The contrast between the *tour de force* treatment of patent-eligibility by Judge Rich in *Bergy* is in sharp contrast to the plural opinions in the notorious *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008)(en banc)(Michel, C.J.).

Drafting Applications to Await the Dawn of a Brighter Day in 2017

Following the drafting guidelines suggested in this monograph should, in the long range, present the best case scenario for the grant of valid claims *at the Patent Office.* That day will not come in the immediate future, but only upon the resignation of the incumbent Under Secretary of Commerce, expected not later than January 2017 upon the inauguration of a new Administration.

The current Patent Office leadership is providing guidance without meaning as manifested by its incomprehensible "guidance" on patent-eligibility.

Thus, just as important as the anti-patentee climate at the Supreme Court is a hapless parallel direction at the Patent Office which has issued the most incomprehensible guidelines on patent-eligibility with citation of *dozens* of Supreme Court and Federal Circuit cases, all with minimal (at most) analysis and where the overall message is to *reject* claims as lacking patent-eligibility.

The incumbent Under Secretary of Commerce is an undeniably brilliant individual as manifested by her academic resume and from all accounts of persons who have worked with her. As noted in her official biography on the Patent Office website, the Under Secretary"[p]rior to joining the USPTO [ ] was Deputy General Counsel for Google and the company's first Head of Patents and Patent Strategy. * * *Before building her legal career, Ms. Lee worked as a computer scientist at Hewlett-Packard Research Laboratories, as well as at the Massachusetts Institute of Technology (M.I.T.) Artificial Intelligence Laboratory. She holds a B.S. and an M.S. in electrical engineering and computer science from M.I.T., as well as a J.D. from Stanford Law School."

Given her *abilities,* it is unmistakably clear the Under Secretary has abdicated her leadership responsibilities in the provision of the patent-eligibility

guidance which stands in sharp relief to her undeniable academic brilliance and analytical skills.

Given the final stages of the Obama Administration which under the Constitution terminates January 20, 2017, there is little hope for any change in long term leadership in the Patent Office in the short time period running up to the inauguration of a new President. While the incumbent will leave office for reasons entirely different from those surrounding her departure from her prior corporate patent leadership position, the result in terms of her place in history will be the same.

Why belabor the point of a single person in terms of a practical understanding of patent-eligibility? The reason is that the Under Secretary wields immense power to shape the direction taken by her examiners. On an optimistic note, patent applications drafted "today" will surely not receive an examination until after the inauguration of a new President. It is therefore important in drafting a new patent application to focus on the case law and practice under that case law, so that claims and applications drafted "today" will be ready for a fresh examination "tomorrow".

§ 1[a] "Fool's Gold" Guidance from the Lee Administration

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.

Of particular concern at the present time is the guidance of Under Secretary Michelle K. Lee which is "fool's gold" for anyone looking for a true solution to the proper claiming of an invention including an element which is either "abstract" or contains a "natural" derivative. Particularly unhelpful is 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 § 10, *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

§ 1[b] Actions for a New Administration in 2017

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* § 10[a], *A Five Step Proposal for Patent Eligibility Examination***.** To be sure, the opportunity to challenge a patent for want of patent-eligibility should remain for post grant review proceedings. *See* § 10[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* § 10[c], *Honoring Supreme Court Rules for Patent Litigation.*

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.*, § 10[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* § § 10[e], *"Markedly Different Characteristics" Guidance.*

§ 1[c] Crafting Patent Applications for Allowance "Tomorrow"

Certainly, the goal for the typical patent applicant is to get his proper scope of protection and not to be a "test case" to challenge the current anti-patent attitude of the Lee Administration. Yet, the basic elements that will be present in such a test case should also be present in the application that should be drafted to take advantage of the results of the test case.

Realistically, many (and perhaps most) Patent Examiners will dissect claims to focus on an element with an "abstract" principle or "natural" product and, because *that* element, *standing alone,* lacks patent eligibility under 35 USC § 101, the claims will be denied *often even without a prior art search* as failing to meet the patent-eligibility test of current Patent Office guidelines. It may well be a different story if the case is appealed to the Patent Trial and Appeal Board where

the individual Administrative Patent Judges are seen to take a relatively independent stance from the administration of the Patent Office.

The immediate patent drafting solution is to craft a patent application that best meets the current case law, and also provides basis for a test case at the Patent Trial and Appeal Board. (A segment of Examiners who *do* reject claims to inventions where they see a shaky foundation for an applicant's appeal may very well back off when an Appeal Brief is filed in a well-presented specification.)

§ 1[c][1] An "Inventive" Claimed Combination

The starting point is to acknowledge, *arguendo,* that the invention *includes* as one element a law of nature, natural phenomenon or an abstract idea which the decisions have recognized as lacking patent- eligibility. *Buysafe, Inc. v. Google, Inc.*, 765 F.3d 1350, 1352 (Fed. Cir. 2014)(Taranto, J.)(quoting *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2354 (2014), quoting *Association for Molecular Pathology v. Myriad Genetics, Inc.,* 133 S.Ct. 2107, 2116 (2013))("The Supreme Court 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.'").

"Claim 1" should be a combination claim that includes at least one "traditional" feature so that one can successfully argue that the *claimed combination* is nonobvious under 35 USC § 103, i.e., the *claimed combination* is "inventive".

To be sure, there are many situations where the addition of a "conventional" element does not create nonobvious (or "inventive") subject matter. But, this is a fact-based determination where the *combination* of the otherwise "conventional" element may be part of a nonobvious *combination* where there is no motivation in the prior art to make that combination.

It is thus a *claimed combination,* including all of its elements in the combination of the claim, that is to be evaluated for patent-eligibility and nonobviousness: The claim is not to be dissected element by element. As explained in the *Adams Battery* case, "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[.]"*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).) For a further discussion of this issue, see § 8[b][2], *The "Inventive" Feature of the Claimed Combination.*

§ 1[c][2] The Claimed Combination as a Whole

Second, the specification and prosecution history should emphasize that the claimed invention comprises *all* of the elements of the claim.

To be sure, there is *dicta* in *Parker v. Flook*, 437 U.S. 584 (1978), seemingly supporting a claim dissection approach. However, in the context of a rich body of case law setting forth the "all elements" rule to claim interpretation, the inconsistent *dicta* should not stand. See § 8[b][1], *Flook versus the "All Elements" Rule.* Also, it is important to note that the *Flook dicta* was repudiated by the Supreme Court shortly thereafter in *Diamond v. Diehr*, 450 U.S. 175 (1981). To the extent that *Flook* stands for the proposition that one may dissect a claim into its constituent elements to determine patent-eligibility based upon the patent-eligibility of one of the components, *Flook* was cabined by *Diamond v. Diehr*, 450 U.S. 175 (1981).

In *Diehr* the Court expressly stated that "[i]n determining the eligibility of [the patent applicants'] claimed process for patent protection under § 101, their *claims must be considered as a whole*. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis." *Diehr*, 450 U.S. at 188.

§ 1[c][1][A] *Chakrabarty* "Straw" Combination Claiming

A *combination* should be claimed that includes subject matter that *is* patent-eligible, to emphasize that the invention is nonobvious, i.e., "inventive". An excellent example of a test case with this strategy is *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980), where the claims that reached the courts were to a microorganism, *per se*, but the application also included a claim to a combination of the microorganism together with *straw*. *In re Bergy*, 596 F.2d 952, 986 (CCPA 1979), *aff'd sub nom Diamond v. Chakrabarty,* 447 U.S. 303 (1980)(claim 31). Certainly, "straw", *per se*, is not "inventive" but the combination with the microorganism was not suggested to one of ordinary skill in the art. *See KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 416 (2007)(discussing the *Adams Battery* case, *United States v. Adams*, 383 U.S. 39 (1966))("The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams' design was not obvious to those skilled in the art.") The claim was

allowed by the Examiner, setting the stage for the appellate challenge with a "given" that the Patent Office acknowledged that the subject matter is "inventive".

By presenting a claim *acknowledged* as representing inventive activity by the Office, the appellate tribunals had, as a *given*, the inventive nature of the claimed subject matter.

§ 1[c][1][B] *Diehr* Claiming Reciting Details of the Innovation

An "apply it" type of software claim that includes no recitation of software details raises a red flag and should be avoided. Instead, a "Diehr claim" should be presented which sets forth the detailed sequence of steps of the software-implemented invention. *Diamond v. Diehr*, 450 U. S. 175 (1981), itself provides an excellent example of such a claim:

1. A method of operating a rubber-molding press for precision molded compounds with the aid of a digital computer, comprising:
providing said computer with a data base for said press including at least,
natural logarithm conversion data (ln),
the activation energy constant (C) unique to each batch of said compound being molded, and
a constant (x) dependent upon the geometry of the particular mold of the press,
initiating an interval timer in said computer upon the closure of the press for monitoring the elapsed time of said closure,
constantly determining the temperature (Z) of the mold at a location closely adjacent to the mold cavity in the press during molding,
constantly providing the computer with the temperature (Z),
repetitively calculating in the computer, at frequent intervals during each cure, the Arrhenius equation for reaction time during the cure, which is

$$\ln v = CZ + x$$

where *v* is the total required cure time,
repetitively comparing in the computer at said frequent intervals during the cure each said calculation of the total required cure time calculated with the Arrhenius equation and said elapsed time, and
opening the press automatically when a said comparison indicates equivalence.
Diehr, 450 U. S. at 179 n.5(reciting claim 1).

To simply provide a generic definition of a computer step, the so-called "apply it" claims, trivializes the invention and almost certainly pushes the court to deny patent-eligibility. As explained by Judge Dyk, "there must be an 'inventive concept' to take the claim into the realm of patent- eligibility. [Alice, 134 S. Ct. at 2355 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297 (2012))]. A simple instruction to apply an abstract idea on a computer

is not enough. *Alice*, 134 S. Ct. 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))." *Intellectual Ventures I LLC v. Capital One Bank*, __ F.3d __, __ (Fed. Cir. 2015), *See also Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344, 1350 (Fed. Cir., 2014)(quoting *Bancorp Servs., LLC v. Sun Life Assurance Co. of Can. (U.S.)*, 687 F.3d 1266, 1276 (Fed.Cir.2012))("[A] claim reciting an abstract idea does not become eligible 'merely by adding the words 'apply it.' ").

§ 1[c][3] Presentation of Two Sets of Claims

To the extent that the applicant has a commercial invention to protect where it is desired to have, say, two features on "claim 1" and not the five or six features in the disclosed embodiment, a useful way of presentation of the invention is to have two sets of claims: The first set appearing on the first page of the claims is to the overall combination with five or six features which *maximizes* the point that the invention is far more than just being directed to a patent-ineligible element. The second set of claims is to the minimum combination necessary to establish patentability.

To the extent that the Examiner requires restriction between the two sets of claims, the claims to the five or six features would be elected as the best short-range chance for allowance. Then, after securing allowance of this elected set (or if and when a test case changes the case law), a divisional application is filed to the minimum combination necessary to establish patentability.

To the extent that the Examiner does *not* make a restriction requirement, the applicant can still file a *voluntary* divisional to the minimum combination necessary to establish patentability and simultaneously cancel such claims in the original application. (Of course, a terminal disclaimer may be necessary for the voluntary divisional.)

§ 1[c][4] A Bare Minimum of Claims should be Presented

For a test case, it is best to present a minimum number of claims, say, three or four, instead of thirty or forty. In addition to enhancing chances on appeal, it is also easier for a Supervisory Primary Examiner to grasp the issues in the case with just a few claims, and perhaps lead to an SPE intervention to allow the case.

§ 1[c][5] A Post-First Action *Background of the Invention*

The applicant should, of course, submit an Information Disclosure Statement within three months from the filing date which identifies (but does not characterize or make arguments about) the prior art. Unlike the usual situation where the applicant is counseled *not* to file a *Background of the Invention, here,* it is advisable after the Examiner's first action to amend the specification to include such a *Background of the Invention* which in a brief paragraph or two explains why the claimed subject matter is "inventive", i.e., nonobvious.

This argument creates a predicate to a Reply Brief before the Patent Trial and Appeal Board in the event the examiner makes an argument that the claimed subject matter is not "inventive".

§ 1[c][6] No "Preemption" of Further Innovation

As explained by Professor Lefstin, "*Mayo* and *Alice* justified subject matter exclusions on utilitarian grounds: because fundamental principles are 'building blocks' for future work, patents on laws of nature or abstract ideas threaten to foreclose more innovation than they promote." Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence of Abstractions,* 16 N. C. J. L. & Tech. 647, 655 (2015)(citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1301-03 (2012); *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014)). *Se also* § 3[b], *"Research Preemption" Confusion in Mayo and Alice.*

§ 1[c][6][A] Disclaimer of the Use of the Element, *Per Se*

To clarify that there is no "preemption" of research by the use of the element which lacks patent-eligibility, may be useful to include in the *Summary of the Invention* that the patent applicant disclaims any coverage of any individual element within the claim and limits his claim to coverage of claimed combination.

Such a disclaimer should not even be necessary, but comes right to the point. As noted in § 8[b][1], *Flook versus the "All Elements" Rule,* the seemingly contradictory view in *Parker v. Flook*, 437 U.S. 584 (1978), was cabined in *Diamond v. Diehr*, 450 U.S. 175 (1981). In that case, the Court said that "[i]n determining the eligibility of [the patent applicants'] claimed process for patent protection under § 101, their claims must be considered as a whole. It is

inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis." *Diehr*, 450 U.S. at 188.

§ 1[c][6][B] "Mueller Disclaimer" to Experiment "On" the Invention

The critical element of the case law since *Bilski* is that a patent on a fundamental principle "preempts" future research. While under historic case law and seemingly everywhere at the appellate level outside the Supreme Court this activity is *outside* the patent grant, it may be useful to include a statement that the patent applicant confirms its understanding that there is a fundamental public right to experiment "on" a patented invention as that terminology is used by Professor Janice M. Mueller, *No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L.Rev. 1 (2001). As confirmation, the *Summary of the Invention* could include a "Mueller Disclaimer", i.e., a statement that the patentee expressly disclaims enforcement of any patent against a member of the public who conducts research "on" the patented invention within the meaning of the Mueller article.

§ 1[d] Crafting Patent Applications for Allowance "Today"

The earliest that one can realistically expect a first action on the merits for a new application will be during the term of a new President in 2017 when there certainly will be a new Under Secretary of Commerce in charge of the Patent Office.

For earliest protection, two sets of claims should be presented with the idea that there will be a restriction requirement. The first set of claims should be as suggested in the previous section. A *second* set of claims that should be elected for first prosecution should be claims to a *combination* of elements including as many elements as necessary to establish that the *claimed combination* is "inventive".

If and when the dust settles and the current anti-patentee wave at the Patent Office and the courts has subsided, a *divisional* application can be filed to the main invention.

§ 1[e] The Selective Case Law Citations of *Ariosa*

It is difficult to conceive of a breakthrough invention that is more "inventive" – nonobvious – than in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). The denial of patent-eligibility in *Ariosa* is keyed to fundamental misstatements of Supreme Court patent law. *Ariosa* dissects the elements of the claimed invention, ignoring both a long line of Supreme Court case law as well as the repudiation of such a focus by the Court itself in *Diamond v. Diehr*. *See* § 8[b][1], *Flook versus the "All Elements" Rule*. The majority also cites the well known statement in *Mayo* that to "apply it" (the software) as the added feature of a claim does not render the invention patent-eligible, while neglecting to include the statement that this conclusion is modified by the fact that the invention is patent-eligible if an "inventive application". *See* § 8[a][4], *Ariosa Mischaracterization of Mayo*.

§ 2. "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 *Household 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).

Professor Lefstin explains that "of all the rationales the Court has invoked for excluding fundamental principles [from the scope of patent-eligibility], the most consistent one is that the Court has been so doing for over 150 years." Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence Of Abstractions*, 16 N. C. J. L. & Tech. 647, 665 (2015)(citing *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) ("We have interpreted § 101 and its predecessors in light of this exception [of fundamental principles] for more than 150 years."); *Mayo*, 132 S. Ct. at 1289, 1293 (citing nineteenth century English and American cases); *Bilski v. Kappos*, 561 U.S. 593, 602 (citing *Le Roy v. Tatham*, 55 U.S. 156 (1853)).).

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, 1293 (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.

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.

The 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).

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§ 2[a] The Nineteenth Century Foundations

§ 2[a][1]. Early English *Household Coal* Case

Household 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.*, 788 F.3d 1371, __ (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 *Household 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); *see also* . 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 *Household 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 174-75.")

Another approach to the *Household* case is explained by Professor Lefstin: "In England, the famous hot-blast cases stood for the doctrine that a patent might preempt all uses of a newly discovered principle, provided that the patentee's disclosure was sufficient to enable application of the principle beyond his

particular means." Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence Of Abstractions*, 16 N. C. J. L. & Tech. 647, 665 (2015).

§ 2[a][2] *Le Roy v. Tatham*, The Lead Pipe Case

In *Bilski*, the Court cites with approval *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 174-75 (1853), for the proposition that "the[ ] exceptions [to patent-eligibility] have defined the reach of the statute as a matter of statutory stare decisis going back 150 years." In *Diamond v. Diehr*, 450 U.S. 175, 185 (1981), the court quotes the same case, 55 U.S. (14 How.) at 175: "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." The same quotation from *Le Roy v. Tatham* is also found in *Parker v. Flook*, 437 U.S. 584, 589 (1978), which itself is a quotation from of *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

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 Household 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.

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 material *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.

As explained in*Busell Trimmer Co v. Stevens*, 137 U.S. 423 (1890) (Lamar, J.):

> 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. *See also* Professor Jeffrey A. Lefstin, *Inventive Application: A History*, 67 Fla. L. Rev. 565, 594-96 (2015).

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 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 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:

"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.

§ 2[a][3] 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).

Those relying upon *O'Reilly* v. *Morse* as denying patent-eligibility have often done so *without* noting that some of the claims of the Morse patent were *upheld*, as explained by Professor 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.

Additionally, as also explained by Professor Mossoff, much of the discussion of this case is colored by applying current meanings to a different practice from a different era.

Professor Lefstin convincingly makes the case that patent "preemption" is neither basis for the denial of the Morse claim 8: "The Court's rejection of Morse's infamous eighth claim was based, not on the objection that Morse was attempting to preempt the use of electromagnetism, but on the objection that Morse had not enabled the use of electromagnetism for communication independent of his particular machinery." Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence Of Abstractions,* 16 N. C. J. L. & Tech. 647, 666 (2015)(footnote omitted).

The Supreme Court several decades later saw the Morse invention in the same light in connection with its consideration of the validity of Alexander Graham Bell's patents to the telephone: "We see nothing in [*O'Reilly v. Morse*] to defeat Bell's claim; on the contrary, it is in all respects sustained by that authority. It may be that electricity cannot be used at all for the transmission of speech except in the way Bell has discovered, and that therefore, practically, his patent gives him its exclusive use for that purpose; but that does not make his claim one for the use of electricity distinct from the particular process with which it is connected in his patent. It will, if true, show more clearly the great importance of his discovery, but it will not invalidate his patent." Jeffrey A. Lefstin, *The Three*

Faces of Prometheus: A Post-Alice Jurisprudence Of Abstractions, 16 N. C. J. L. & Tech. 647, 666 n.82 (2015)(quoting *The Telephone Cases*, 126 U.S. 1, 535(1888)).

Nineteenth century scholars, including Professor William Robinson, shared the same viewpoint as expressed in *The Telephone Cases*. Lefstin, 16 N. C. J. L. & Tech. at 666-67 (quoting William C. Robinson, THE LAW OF PATENTS FOR USEFUL INVENTIONS 44 (1890)).

Echoing the views of a variety of scholars who have failed to point out the distinctions noted by Professor Mossoff, 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).

The Mossoff view is well stated in an *amicus* brief filed on behalf of twenty three academics. *See Brief of Amicus Curiae Twenty-Three Law Professors in Support of Appellants' Petition for Rehearing En Banc, Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Fed. Cir. No. 2014-1139 (August 27, 2015)(on behalf of the twenty-three Professors Dan L. Burk, Bernard Chao, Ralph D. Clifford, Christopher A. Cotropia, Gregory Dolin, Richard A. Epstein, Christopher Frerking, Yaniv Heled, Timothy Holbrook, Christopher M. Holman, Gus Hurwitz, Mark D. Janis, Adam Mossoff, Sean M. O'Connor, Kristen Osenga, Lee Petherbridge, Michael Risch, Mark F. Schulz, Sean B. Seymour, Ted Sichelman, Brenda M. Simon, Shine Tu, and Saurabh Vishnubhakat), pp. 5-7 (discussing *O'Reilly v. Morse* and its analysis by Adam Mossoff, *O'Reilly v. Morse* (August 18, 2014), *available at* http://ssrn.com/abstract=2448363). What is remarkable is the *absence* of the names of a community of scholars who continue to boldly and uncritically cite *O'Reilly v. Morse* as basis to deny patent-eligibility of inventions such as that in the *Ariosa* case.

A view consistent with Professor Mossoff is found in a dissent in the *Bilski* case:

> 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.*

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, one from more the 165 years ago:

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)).

§ 2[a][4] 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]n 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).

"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.

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).

§ 2[b] 'Modern Mischaracterization of Precedent

The Supreme Court in recent years has repeatedly mischaracterized nineteenth century English and American case law as establishing exceptions to patent-eligibility under 35 USC § 101 dating back 150 years. See, e.g Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. 565, 594-96 (2015); *see also* Adam Mossoff, *O'Reilly v. Morse*, George Mason University Law and Economics Research Paper Series (2014).

§ 2[b][1] "Too Much" Patent Protection vs. Real World Realities

Per Justice Breyer, "sometimes ***too much*** patent protection can impede rather than `promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection." *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126 (2006) (Breyer, J., joined by Stevens, Souter, JJ., dissenting from dismissal of writ of certiorari) (emphasis in original).

The Breyer argument that there may be "too much patent protection" has been uncritically referenced in subsequent opinions both at the Supreme Court and the Federal Circuit. In *Bilski* Justice Stevens reiterated the Breyer argument:

"[E]ven if patents on business methods were useful for encouraging innovation and disclosure, it would still be questionable whether they would, on balance, facilitate or

impede the progress of American business. For even when patents encourage innovation and disclosure, 'too much patent protection can impede rather than 'promote the Progress of . . . useful Arts.'' *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.,* 548 U. S. 124, 126-127 (2006) (Breyer, J., dissenting from dismissal of certiorari). Patents 'can discourage research by impeding the free exchange of information,' for example, by forcing people to 'avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented' methods. Id., at 127. Although '[e]very patent is the grant of a privilege of exacting tolls from the public,' *Great Atlantic* [*& Pacific Tea Co*. v. *Supermarket Equipment Corp*., 340 U. S. 147, 154 (1950)](Douglas, J., concurring), the tolls of patents on business methods may be especially high."

Bilski v. Kappos, 561 U. S. 593 (2010)(Stevens, J., joined by Ginsburg, Breyer, Sotomayor, concurring in the judgement). Circuit Judge Mayer made a parallel argument in the *en banc* rehearing in *Bilski*:

'[S]ometimes too much patent protection can impede rather than `promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection.' *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.,* 548 U.S. 124, 126 (2006) (Breyer, J., joined by Stevens and Souter, JJ., dissenting from dismissal of writ of certiorari) (emphasis in original). This is particularly true in the context of patents on methods of conducting business. Instead of providing incentives to competitors to develop improved business techniques, business method patents remove building blocks of commercial innovation from the public domain. [Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?,* 16 Santa Clara Computer & High Tech. L.J. 263, 275-77 (2000)].. Because they restrict competitors from using and improving upon patented business methods, such patents stifle innovation. When 'we grant rights to exclude unnecessarily, we ... limit competition with no quid pro quo. Retarding competition retards further development.' [Malla Pollack, *The Multiple Unconstitutionality of Business Method Patents,* 28 Rutgers Computer & Tech. L.J. 61, 76 (2002)]. 'Think how the airline industry might now be structured if the first company to offer frequent flyer miles had enjoyed the sole right to award them or how differently mergers and acquisitions would be financed ... if the use of junk bonds had been protected by a patent.' [Dreyfuss, *supra* at 264]. By affording patent protection to business practices, 'the government distorts the operation of the free market system and reduces the gains from the operation of the market.' [James S. Sfekas, *Controlling Business Method Patents: How the Japanese Standard for Patenting Software Could Bring Reasonable Limitations to Business Method Patents in the United States*, 16 Pac. Rim. L. & Pol'y J. 197, 214 (2007)]

In re Bilski, 545 F.3d 943, 1006 (Fed. Cir. 2008)(en banc)(Mayer, J., dissenting), *further proceedings sub nom Bilski v. Kappos*, 561 U. S. 593 (2010). Subsequently in the *Myriad* case, Judge Moore considered the same argument but with a more realistic view of the real world of technology:

The dissent suggests that 'this may well be one of those instances in which 'too much patent protection can impede rather than 'promote the Progress of Science and useful Arts.' ' ' Dissent at 1380 (quoting *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc*., 548 U.S. 124, 126 (2006) (Breyer, J., dissenting from dismissal of writ as improvidently granted)). Yet the biotechnology industry is among our most innovative, and isolated gene patents, including the patents in suit, have existed for decades with no evidence of ill effects on innovation. See David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 Tex. L.Rev. 1677, 1681 (2007) ('The existing empirical studies find few clear signs that the patenting of biotechnology inventions is adversely affecting biomedical innovation.'); *id*. at 1729 (concluding 'that overall biotechnology innovation is not being impaired by the growth in patents issued').

With respect, whether in the real world of commerce or the basic Supreme Court case law established in the nineteenth century, the quoted statement represents a mythology divorced from the real world of commerce and innovation.

In the limited circumstance of a hypothetical laboratory experiment where there is neither any competing technology to a pioneer invention nor the possibility for any room for improvement in that pioneer invention, one may assume, *arguendo*, that this Breyer-eye view of the patent system may be correct. But that is rarely – if ever – the case.

Even with the broadest imaginable protection for a new innovation, it is difficult for a new technology to enter the marketplace. In the usual situation, a pioneer invention is introduced with great difficulty to challenge the *status quo* of an established industry. The established technology is supported by numerous factories and distribution networks that are at best difficult for a newcomer to penetrate. The innovator has difficulty breaking down the barriers of the establishment to enter the distribution system and to penetrate the consumer base that is subject to a barrage of advertisements and other advantages for the established technology.

Even facing the scope of a broad pioneer patent, however, there is every incentive for competitors to make further innovations. Some of these efforts will result in a further breakthrough outside the scope of the pioneer patent. Others may well fall within the scope of the pioneer's patent, but patent protection for the subsequent innovator will block the pioneer from practicing that innovation, absent a license from the subsequent innovator.

Furthermore, the subsequent innovator will in the end have a monopoly on its new technology versus the pioneer, because the pioneer's patent will expire at a point in time when the subsequent innovator's patent will remain in force. Cf. *Transparent-Wrap Mach. Corp. v. Stokes & Smith Co.*, 329 U.S. 637, 642 (1947)(Douglas, J.)("An improvement patent may *** have great strategic value. For it may, on expiration of the basic patent, be the key to a whole technology. One who holds it may therefore have a considerable competitive advantage.")

It must also be remembered that one cannot view the pioneer patent and the subsequent innovator's patent *in vacuo,* but must consider the patents in light of the overall marketplace where there will be competing technologies. It makes great sense in this real world scenario for the pioneer and the subsequent innovator to cross-license their technology to each other so that both can better compete with the alternative, competing technologies. (Or, it may make sense for one of the two patentees to buy the other one out.)

The Supreme Court in its early jurisprudence recognized the importance of broad patents to *stimulate* the Progress of the Useful Arts. Thus, instead of minimizing the scope of protection for a pioneer invention, the Supreme Court did just the opposite: It gave broader protection beyond the literal wording of the claims of the pioneer patent through an expansive doctrine of equivalents.

§ 2[b][2] Early Supreme Court Recognition of the Need for Broad Protection

Case law developed beginning in the second half of the nineteenth century firmly established the principle that a pioneer patent should be given broad protection. *See, inter alia, Morley Sewing-Machine Co. v. Lancaster,* 129 U. S. 263 (1889); *Miller v. Eagle Mfg. Co*., 151 U. S. 186 (1894); *Cimiotti Unhairing Co. v. American Fur Refining Co*., 198 U.S. 399 (1905); *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 (1908).

In *Miller v. Eagle* , quoting *Morley Sewing-Machine,* the Court explained:

"The range of equivalents depends upon the extent and nature of the invention. If the invention is broad or primary in its character, the range of equivalents will be correspondingly broad, under the liberal construction which the courts give to such inventions. The doctrine is well stated in *Morley Sewing-Machine Co. v. Lancaster*, 129 U. S. 263, 273 (1889), where it is said: 'Where an invention is one of a primary character, and the mechanical functions performed by the machine are, as a whole, entirely new, all subsequent machines which employ substantially the same means to accomplish the same result are infringements, although the subsequent machine may contain improvements in the separate mechanism which go to make up the machine.'"

Miller v. Eagle Mfg. Co., 151 U. S. at 207. In *Cimiotti Unhairing* the Court explained:

"In determining the construction to be given to the claim in suit * * * it is necessary to have in mind the nature of this patent, its character as a pioneer invention or otherwise, and the state of the art at the time when the invention was made. It is well settled that a greater degree of liberality and a wider range of equivalents are permitted where the patent is of a pioneer character than when the invention is simply an improvement, may be the last and successful step, in the art theretofore partially developed by other inventors in the same field. Upon this subject it was said by this court (*Westinghouse* v. *Boyden Power Brake Co.* 170 U. S. 537 (1898), quoted with approval in *Singer Mfg. Co.* v. *Cramer*, 192 U. S. 265, 276-77(1904)):

""To what liberality of construction these claims are entitled depends to a certain extent upon the character of the invention, and whether it is what is termed in ordinary parlance a 'pioneer.' This word, although used somewhat loosely, is commonly understood to denote a patent covering a function never before performed, a wholly novel device, or one of such novelty and importance as to mark a distinct step in the progress of the art, as distinguished from a mere improvement or perfection of what had gone before. Most conspicuous examples of such patents are: The one to Howe of the sewing machine; to Morse of the electric telegraph; and to Bell of the telephone. The record in this case would indicate that the same honorable appellation might safely be bestowed upon the original air-brake of Westinghouse, and perhaps also upon his automatic brake. In view of the fact that the invention in this case was never put into successful operation, and was, to a limited extent, anticipated by the Boyden patent of 1883, it is perhaps an unwarrantable extension of the term to speak of it as a 'pioneer,' although the principle involved subsequently and through improvements upon this invention became one of great value to the public.'"

Cimiotti Unhairing Co. v. American Fur Refining Co., 198 U.S. 399, 406-07 (1905).

Three years later in *Continental Paper Bag*, the Court explained that "[t]he range of equivalents [beyond the literal scope of protection] depends upon the extent and nature of the invention. If the invention is broad or primary in its character, the range of equivalents will be correspondingly broad, under the liberal construction which the courts give to such inventions." *Continental Paper Bag.*, 210 U.S. at 414, quoting *Miller v. Eagle*, 151 U. S. at 207.

§ 2[b][3] Recent Supreme Court Mischaracterization of Case Law

In case law created *sua sponte* without regard even to the very precedent it cites, the Supreme Court has said in *Bilski v. Kappos*, 561 U. S. 593 (2010), that:

"The Court has kept this 'constitutional standard' in mind when deciding what is patentable subject matter under §101. For example, we have held that no one can patent 'laws of nature, natural phenomena, and abstract ideas.' [*Diamond v. Diehr,* 450 U.S. 175, 185(1981)]. These 'are the basic tools of scientific and technological work,' [*Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)], and therefore, if patented, would *stifle the very progress* that Congress is authorized to promote, see, *e.g., O'Reilly* [*v. Morse,* 56 U.S. 62, 113 (1853)](explaining that Morse's patent on electromagnetism for writing would preempt a wide swath of technological developments).

Precisely what does *Benson* say about "preemption" at the page cited in *Bilski*?

"The Court stated in *Mackay Co. v. Radio Corp*., 306 U.S. 86, 94 that '(w)hile a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.' That statement followed the longstanding rule that '(a)n idea of itself is not patentable.' *Rubber-Tip Pencil Co. v. Howard*, 20 Wall. (87 U.S.) 498, 507. '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,* 14 How. (55 U.S.) 156, 175. 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. As we stated in *Funk Bros. Seed Co. v. Kalo Co*., 333 U.S. 127, 130, '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.'"

Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

Precisely what does *Diehr* say about "preemption" at the page cited in *Bilski*? Nothing, directly, but indirectly, *arguendo*, preemption could be understood as implicated. As stated in *Bilski:*

"'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*, 14 How. 156, 175 (1853). Only last Term, we explained:

" '[A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that E = mc^2; nor could Newton have patented the law of gravity. Such discoveries are

'manifestations of . . . nature, free to all men and reserved exclusively to none.' [*Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)], quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, [333 U.S. 127, 130 (1948)]."

What does *O'Reilly v. Morse,* 56 U.S. 62, 113 (1853), say?

"If [ ]his claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.

Nor is this all, while he shuts the door against inventions of other persons, the patentee would be able to avail himself of new discoveries in the properties and powers of electro-magnetism which scientific men might bring to light. For he says he does not confine his claim to the machinery or parts of machinery, which he specifies; but claims for himself a monopoly in its use, however developed, for the purpose of printing at a distance. New discoveries in physical science may enable him to combine it with new agents and new elements, and by that means attain the object in a manner superior to the present process and altogether different from it. And if he can secure the exclusive use by his present patent he may vary it with every new discovery and development of the science, and need place no description of the new manner, process, or machinery, upon the records of the patent office. And when his patent expires, the public must apply to him to learn what it is. 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 opinion that the claim is too broad, and not warranted by law*."

[emphasis added]. Thus, while most of the claims in *O'Reilly v. Morse* were *sustained* by the Supreme Court, the one lone claim that was invalidated was done so on the basis of undue breadth as opposed to patent-eligibility. *See also* Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. 565, 597 (2015) ("Morse is about disclosure and scope, not patent-eligible subject matter.")

§ 2[b][4] Federal Circuit Adoption of the Breyer Mythology

There are several examples where jurists have referred to the "150 years" of *stare decisis* concerning patent-eligibility:

The second longest serving active member of the court with more than forty years of patent experience both corporate and as a member of the court 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).

A dissent in *Myspace* includes the statement that "[p]rohibitions 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. 3218, 3225 (2010)).

A panel in *Cybersource* stated that "[t]he Court noted that these judicially created exceptions 'have defined the reach of the statute as a matter of statutory stare decisis going back 150 years,' and are ' 'part of the storehouse of knowledge of all men ... free to all men and reserved exclusively to none.'" *Cybersource Corp.. v. Retail Decisions Inc*., 654 F.3d 1366, 1369-70 (Fed. Cir. 2011)(Dyk, J.)(quoting *Bilski v. Kappos*, 130 S.Ct. 3218, 3225 (2010), quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127, 130 (1948)).

More recently, yet another panel stated that "[t]he Supreme Court 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.'" *Buysafe, Inc. v. Google, Inc.*, 765 F.3d 1350, 1352 (Fed. Cir. 2014)(Taranto, J.)(quoting *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2354 (2014), quoting *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2116 (2013)).

It is without question the responsibility of an appellate court to follow *the law* as set forth by the Supreme Court. It is yet another matter for an appellate court to swallow Supreme Court Kool-Aid as to factual predicates for its jurisprudence. If the Court says black is white, the Court is wrong: Black is always black and never white.

Yet, the Federal Circuit has uncritically accepted factual predicates that are both wrong as a matter of the real world and which furthermore are in conflict with the earlier Supreme Court case law that the Federal Circuit has generally refrained from consideration in its opinions. One dissent at the Federal Circuit notes:

Our patent system *** does not award a monopoly that precludes others from using the basic procedures of scientific investigation to study the same phenomenon. *See Bilski* [*v. Kappos,* 130 S.Ct. 3218, 3253 (2010)] (Stevens, J., concurring) (Patents on laws of nature, natural phenomena, and abstract ideas "would stifle the very progress that Congress is authorized to promote."). * * * When, as here, the claims so clearly offend the constitutional imperative to promote the useful arts, where they preempt all application of a principle or idea, it is entirely appropriate to hold them unpatentable subject matter before reaching anticipation, obviousness, or any other statutory section that might also prove invalidity.

Classen Immunotherapies Inc. v. Idec, 659 F.3d 1057, 1080 (Fed. Cir. 2011)(Moore, J., dissenting)

In yet another dissent, it is stated that:

"'[S]ometimes *too much* patent protection can impede rather than `promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection.' *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.,* 548 U.S. 124, 126 (2006) (Breyer, J., joined by Stevens and Souter, JJ., dissenting from dismissal of writ of certiorari) (emphasis in original). This is particularly true in the context of patents on methods of conducting business. Instead of providing incentives to competitors to develop improved business techniques, business method patents remove building blocks of commercial innovation from the public domain. [Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 Santa Clara Computer & High Tech. L.J. 263, 275-77 (2000)]. Because they restrict competitors from using and improving upon patented business methods, such patents stifle innovation."

In re Bilski, 545 F.3d 943, 1006 (Fed. Cir., 2008)(en banc)(Mayer, J., dissenting), *aff'd sub nom Bilski v. Kappos,* 561 U.S. 593 (2010). *See also Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 719 (Fed. Cir., 2014)(Mayer, J., concurring)("Subject matter eligibility challenges provide the most efficient and effective tool for clearing the patent thicket, weeding out those patents that stifle innovation ***.")

The idea that patents "stifle" research is reprised in *Genetics Institute:*

"My fear is that the majority's rule could ultimately stifle the important incentives for innovation that drive our patent system. *** [T]he majority has effectively allowed Novartis to broaden the scope of its claims to usurp the fruits of research by the subsequent, independent inventors who actually discovered the location of vWF binding in the a3 region. By ruling that a patentee can have a monopoly on the later-discovered properties of a structure merely by claiming the structure itself, the majority's decision would discourage others from investing in future research into that very structure."

Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc., 655 F.3d 1291, 1318 (Fed. Cir. 2011)(Dyk, J., concurring-in-part and dissenting-in-part)

The second senior-most active member of the Federal Circuit expressed his level of knowledge in the *CLS Bank* case:

"[E]ven inventions that fit within one or more of the [§ 101] statutory categories are not patent eligible if drawn to a law of nature, a natural phenomenon, or an abstract idea. The underlying concern is that patents covering such elemental concepts would reach too far and claim too much, on balance obstructing rather than catalyzing innovation. But danger also lies in applying the judicial exceptions too aggressively because 'all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.'"

CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1277 (Fed. Cir., 2013)(en banc)(per curiam)(Lourie, J., joined by Dyk, Prost, Reyna, Wallach, JJ., concurring), *subsequent proceedings sub nom Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014), quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1293 (2012).

Much earlier, one member of the court said that "sometimes *too much* patent protection can impede rather than `promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection." *In re Bilski*, 545 F.3d 943, 1006 (Fed. Cir., 2008) (en banc)(Mayer, J., dissenting), *subsequent proceedings sub nom Bilski v. Kappos*, 561 U.S. 593 (2010)(quoting *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126 (2006) (Breyer, J., joined by Stevens and Souter, JJ., dissenting from dismissal of writ of certiorari)) emphasis in original).

A senior member of the court has expressed reservations to broad claims in the context of the *Myriad* case:

"[I[t is important to consider the effects of such broad patent claims on the biotechnology industry. While [the patentee] has emphasized the biotechnology industry's need of patent protection to encourage and reward research in this difficult and important field, there is another side to the coin. Broad claims to genetic material present a significant obstacle to the next generation of innovation in genetic medicine—multiplex tests and whole-genome sequencing. New technologies are being developed to sequence many genes or even an entire human genome rapidly, but firms developing those technologies are encountering a thicket of patents. Secretary's Advisory Comm. on Genetics, Health, and Society, Dep't of Health & Human Servs., *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* 49–62 (2010). In order to sequence an entire genome, a firm would have to license thousands of patents from many different licensors. *See id.* at 50–51. Even if many of those patents include claims that are invalid for anticipation or obviousness, the costs involved in determining the scope of all of those patents could be prohibitive. *See id.* at 51–52; Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the*

Anticommons in Biomedical Research, 45 Hou. L.Rev. 1059, 1076–1080 (2008) (concluding that existing studies 'have focused relatively little attention on downstream product development' and that interviews accompanying those studies suggest that, though smaller than initially feared, the costs associated with the patent thicket are 'quite real in the calculations of product-developing firms'). In light of these considerations, this may well be one of those instances in which'*too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts.' " *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.,* 548 U.S. 124, 126 (2006) (Breyer, J., dissenting from dismissal of writ as improvidently granted).

The *Myriad* Case, *The Ass'n For Molecular Pathology v. U.S. Patent and Trademark Office* , 653 F.3d 1329, 1379-80 (Fed. Cir., 2011)(Bryson, J., concurring in part and dissenting in part), *subsequent proceedings sub nom Association for Molecular Pathology v. Myriad,* 133 S. Ct. 2107 (2013).

In the same case, a differing view was expressed by a less senior member of the court:

"The dissent suggests that 'this may well be one of those instances in which 'too much patent protection can impede rather than 'promote the Progress of Science and useful Arts. ' " Dissent at 1380 (quoting *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.,* 548 U.S. 124, 126 (2006) (Breyer, J., dissenting from dismissal of writ as improvidently granted)). Yet the biotechnology industry is among our most innovative, and isolated gene patents, including the patents in suit, have existed for decades with no evidence of ill effects on innovation. *See* David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate,* 85 Tex. L.Rev. 1677, 1681 (2007) ('The existing empirical studies find few clear signs that the patenting of biotechnology inventions is adversely affecting biomedical innovation.'); *id.* at 1729 (concluding 'that overall biotechnology innovation is not being impaired by the growth in patents issued')."

The *Myriad* Case, *The Ass'n For Molecular Pathology v. U.S. Patent and Trademark Office* , 653 F.3d 1329, 1371(Fed. Cir. 2011)(Moore, J., concurring), *subsequent proceedings sub nom Association for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013).

§ 2[b][5] Safeguards Against Overly Broad Patent Protection

Even allowing for a broad construction of patents of a pioneer nature, there remain cases where broad claims are *properly* denied as they fail to meet the ordinary statutory requirements for patentability.

For example, a claim may be so broad as to read on an embodiment that is obvious within the meaning of 35 USC § 103: "But '[g]ranting patent protection

to advances that would occur in the ordinary course without real innovation retards progress.'" *In re Kubin*, 561 F.3d 1351, 1361 (Fed. Cir. 2009)(Rader, J.)(citing *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007)). "Were it otherwise patents might stifle, rather than promote, the progress of useful arts." *Id.* (quoting *KSR*, 550 U.S. at 427). Or, the claims may be so broad that the claims read on embodiment that are not enabled by the inventor's disclosure: "[35 USC § 112] requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art." *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970).

§ 2[b][6] *Funk v. Kalo* Mythology of the "Natural" Product[*]

I think that I shall never see
A poem as lovely as a tree. …
Poems are made by fools like me,
But only God can make a tree.

Joyce Kilmer, *Trees* (1913)

Justice Douglas, in an era pre-dating the Watson and Crick discovery of the double helix, had a similar view of science as expressed in *dicta* in *Funk Bros. Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127, 130-31 (1948)[**], denied patentability of Bond's claim to a novel combination of microorganisms:

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[*] Portions of this section are borrowed from Harold C. Wegner, *Mayo v. Prometheus: Implications for "Composition[s] of Matter"* (April 27, 2012), available at www.GrayOnClaims.com/hal.

[**] Turning the clock back to the time of *Funk v. Kalo*, not only was there no comprehension of modern science, but even if there had been scientific knowledge available, *Funk v. Kalo* was a minor precedent *at the time* where little thought went into the opinion itself, if the time spent on the case is any indicator. At the time of the decision itself, *Funk v. Kalo* was a sideshow to the main patent event of the day, the seventeen month gestation of the *Line Material* patent antitrust case. *United States v. Line Material Co.*, 333 U.S. 287 (1948). The *Line Material* patent antitrust case was pending at the Court for seventeen months; the Court devoted two days of of argument to *Line Material* (November 12-13, 1947); and the final was given on March 8, 1948. *Line Material*, 67 S.Ct. 113 (Mem) (Oct. 21, 1946)(noting probable jurisdiction). In contrast thereto, *Funk v. Kalo* was decided just three weeks earlier on February 16, 1948, just a month after the argument on January 13, 1948. *United States v. Line Material Co.*, 333 U.S. 287 (1948), *probable jurisdiction noted, Line Material*, 67 S.Ct. 113 (Mem) (Oct. 21, 1946).

We have here only product claims. Bond does not create 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 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. [citations omitted] The Circuit Court of Appeals thought that Bond did much more than discover a law of nature, since he made an 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.

The serious scientist-patent scholar, Dan L. Burk, has demonstrated the futility of trying to define an invention on whether it is or is not drawn from the natural world: The penchant to deny patent-eligibility because an invention relates to a "natural" product creates a slippery slope with no end:

"[E]verything we produce—pipes, computers, recombinant plasmids, breakfast cereals, nectarines, Saran Wrap, Velcro —is a product drawn from elements of the material world; all embody and conform to the same fundamental physical laws of motion, gravitation, conservation, symmetry, relativity, thermodynamics, and electromagnetism. Human artifacts (and humans) are drawn from nature and return to nature in one form or another. Indeed, I am not entirely certain what it means to say that the products of human activity are ever *not* a part of nature; beavers build dams, bees build hives, and humans build semiconductor chips. It's all quite natural.

* * *

"In its native environment, the constrained helical DNA molecule quite literally ties itself into knots. This same effect can easily be seen in the handset cords of desktop telephone sets; the cords are generally helical, and inevitably coil themselves into tangles when the handset is replaced into the cradle after a few calls. The only feasible way to unwind the cord is to release the constraints on the cord by dangling the handset

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As a precedent judged either contemporaneously or for more than twenty years thereafter, *Funk v. Kalo* is a minor case of essentially no importance. Up until the author of *Funk v. Kalo* cited the case in his opinion in *Gottschalk* v. *Benson*, 409 U.S. 63 (1972 (more than twenty years later) the case was manifestly a minor blip on the stare decisis radar screen: Neither the Supreme Court nor any Circuit Court even *cited* the case in that period (although several Circuit Court opinions cite the *Circuit Court* opinion below for an issue not reversed by the Supreme Court in *Funk v. Kalo*).

and allowing it to spin freely. DNA winds itself into coils in exactly the same fashion. This coiled structure of the helix, whether seen in telephone cords or in macromolecules, can be mathematically described as two variables termed the *twist* and *writhe* of the strand.

"In the molecule's natural state, this molecular tangling is constrained by a lattice of scaffolding proteins, as well as by ambient globular proteins that hold the strands open, closed, or stable depending on the state of a given molecular function, such as transcription or replication. These associated structures do not accompany the nucleotide strand into artificial settings such as the laboratory; the structural constraints are removed during the extraction process, and are of course never present for molecules generated by artificially initiated reverse transcription. Judge Lourie [in the *Myriad* case, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012),] is correct that snipping a piece out of the chromosome makes a difference, but it is not simply in the bonds at the ends of the strand; the twist and writhe found in the wild are eliminated.

"A DNA molecule outside the cellular environment is in fact characterized by a large number of other differences—the pitch (or 'wind') of the helix, the ionic shell surrounding the molecule, the charge of the phosphate backbone of the molecule, the manner in which the molecule folds or 'sticks' to itself and other molecules—depending on the medium in which it is immersed. Indeed, laboratory conditions such as pH—acidity—and buffer composition are generally chosen precisely in order to avoid the natural configuration of the molecules; the strands are nearly impossible to work with when wrapped up in knots around themselves.

"Such molecular configurations matter. They define the physical characteristics, and hence the biological function, of the molecules. The primary sequence is important because it is a key factor in defining the molecule's secondary and tertiary configurations; it is necessary to molecular function, but not sufficient. Moving the substance out of the cell inevitably alters it in ways not reflected by the primary sequence.

"The perverse corollary to this truth is that the product of nature doctrine invites its devotees to indulge in a mad search for some aspect of an invention that might be considered *un*natural. It should come as no surprise that the primary focus of the arguments presented in [the *Myriad* case] have centered upon finding some aspect of the DNA molecules that might be considered man made. For example, both parties disputed the significance of the differences between genomic coding regions and the sequence as found in the complementary DNA (cDNA), which is derived from RNA transcripts. Eukaryotic coding sequences typically have long intervening sequences, or introns, that are not included in the production of RNA transcripts, and so appear in the native coding sequence, but are not in reverse transcribed into the cDNA that is generally used in the laboratory."

Dan L. Burk, *Edifying Thoughts of a Patent Watcher: The Nature of DNA*, 60 UCLA L. Rev. Disc. 92 (2013)(original emphasis)(footnotes omitted). (The Burk article was prepared following the grant of *certiorari* in the *Myriad* case but before the merits decision in that case.)

♦ ♦ ♦

§ 3. *ALICE* MYTHOLOGY OF A RESEARCH "PREEMPTION"

As explained by Professor Lefstin, "*Mayo* and *Alice* justified subject matter exclusions on utilitarian grounds: because fundamental principles are 'building blocks' for future work, patents on laws of nature or abstract ideas threaten to foreclose more innovation than they promote." Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence of Abstractions,* 16 N. C. J. L. & Tech. 647, 655 (2015)(citing *Mayo,* 132 S. Ct. at 1301-03; *Alice,* 134 S. Ct. at 1355.)

One can only agree that experimentation "on" a patented invention is a central aspect to reach the goal that a patent system Promote the Progress of *** the Useful Arts. But, this right should not be limited to the narrow area of Supreme Court "preemption" case law but should be open to *all* technologies of every form.

Without the right to experiment "on" a patented invention, this would mean that once a patent was issued, the rest of the world would have to wait the fifteen or so years for the patent to expire before conducting research (or whatever period remains of the twenty years from the filing date). It is absurd to think that the wheels of progress would by stymied for a generation to await the expiration of patents before proceeding further. But, it has always been the law that there is an *immediate* right to experiment "on" a patented invention that can be traced back to the early nineteenth century writings of Joseph Story. *See* § 3[a][1], *The Story Line of Case Law* (discussing *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) (Story, J.)(riding circuit)).

It is the aberrant *Deuterium* line of Federal Circuit case law that leaves open a blistering sore that denies any right to conduct research on a patented invention, whether a "basic" invention or a breakthrough pioneer invention, or *any* invention having nothing to do with an "abstract" idea or a product of nature. The scar of *Deuterium* needs to be erased so that *everyone* can experiment "on" a patented invention. *See* § 3[d], *Dueterium, a Fantasyland Solution to a Real Problem* (noting the policy considerations in *Merck KGaA v. Integra Lifesciences I, Ltd.,* 545 U.S. 193 (2005), as discussed in Wegner, *Post*-Merck *Experimental Use and the "Safe Harbor,"* 15 Fed. Cir. B.J. 1, 3 (2005)).

Additionally, everyone can use an invention for *any* purpose without fear of an injunction in the interval between the 18 month publication of the application and the often much later grant of a patent. Even during the term of a patent, a German, Japanese or other foreign enterprise may experiment "on" a patented

invention under local patent laws, thus promoting research offshore at the expense of domestic American industry. As a *de facto* practice major domestic American pharmaceutical companies routinely experiment on recently patented inventions to see how they operate and to compare them to the state of the art.

A leading academic and coauthor of a major patent casebook along with Circuit Judge Rader has said that a supporter of the result in *Deuterium* is "a person who '[s]urely … needs the help of a mental health professional.'" *Id.* at 8-9 (quoting 3 Martin J. Adelman *et al.*, PATENT LAW PERSPECTIVES § 3.6[2] at 3-78.2(3) (2nd ed. 2005)).

One member of the Federal Circuit, a former Vice-President for intellectual property of a major American pharmaceutical concern, knows full well that it is standard practice in some industries that operate at the highest ethical level to routinely experiment "on" recently patented technology; yet, at the same time this jurist denies the existence of a right to experiment on a patented invention. *See* **§** 3[e], *Experimentation "On" Technology: The Industry Norm*.

§ 3[a] Constitutional *Right* To Experiment on a Patented Invention

The Constitutional objective of the patent system is to *encourage* research through patent disclosures. Manifestly, 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.

§ 3[a][1] The Story Line of Case Law

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:

" '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").

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, P*rotecting 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.*

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 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).

§ 3[a][2] Broad Patents "Promote the Progress of *** the Useful Arts"

Historic Supreme Court precedent supporting broad protection for pioneer innovators is in marked contrast to the notorious statement by a current member of the Court that there can be "too much" patent protection. *See* § 2[b][1], *"Too Much" Patent Protection vs. Real World Realities* (discussing *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126 (2006) (Breyer, J., joined by Stevens, Souter, JJ., dissenting from dismissal of writ of certiorari)(arguing that "*too much* patent protection can impede rather than `promote the Progress of Science and useful Arts[.]"')

In the first instance, the Constitutional objective is to *promote follow-on research* and not to eviscerate the commercial exploitation of an invention by limiting the scope of commercial protection. Follow-on research is facilitated by the right to experiment "on" a patented invention. Whether the patentee's competitors should have a free ride to compete by an eviscerated scope of patent protection, if anything, is a *discouragement* to the Constitutional goal to Promote the *Progress* of the Useful Arts.

In fact, the nineteenth century Supreme Court, far from saying that patent protection should be carefully metered out – to avoid "too much" protection – said

just the opposite. For a pioneer invention *broader* protection was to be given to such an invention. Thus, the early Supreme Court recognized that the scope of protection beyond the literal wording of claims should be proportional to the level of the invention, with the pioneer inventor receiving the broadest scope of protection beyond the literal wording of the claim. *See* § 2[b][2], *Early Supreme Court Recognition of the Need forBroad Protection* (citing *Morley Sewing-Machine Co. v. Lancaster*, 129 U. S. 263 (1889); *Miller v. Eagle Mfg. Co.*, 151 U..S. 186 (1894); *Cimiotti Unhairing Co. v. American Fur Refining Co*., 198 U.S. 399 (1905); *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 (1908)).

To be sure, there is aberrant Federal Circuit case law denying the right to experiment "on" a patented invention. *See* § 3[c], *Deuterium Ghost at the Federal Circuit* (discussing *Deuterium Corp. v. United States*, 19 Cl.Ct. 624 (Cl.Ct.1990)(Rader, J.))(denying the existence of a right to experiment on a patented invention by 'question[ing] whether any infringing use can be de minimis.'") Yet, this aberration is contrary to the historic right to experiment "on" a patented invention that dates back to the early case law of Joseph Story, riding circuit, that patents do not at all preempt research on a patented invention.

While the patentee, alone, has the right to exploit the specifically patented technology, the patentee needs every encouragement, given that in almost every case the patentee will be attempting to break into markets long dominated by older technologies which have the advantage of establish production, distribution, advertising and recognition by the public.

By giving the pioneer inventor a broad scope of protection, this furthermore encourages breakthrough technological advances because of the limitations on commercial exploitation of an invention which is at the heart of the patent right: With respect to *commercial* domination that at first blush appears to be the result of a broad patent grant, this view fails to take into consideration the fact that *commercial* domination is not part of the Constitutional objective to Promote the Progress of the Useful Arts. But, in fact, to the extent that a new, pioneer patentee *does* obtain an exclusive patent position of broad scope, this provides a very strong incentive to competitors to feverishly expend resources to design around the claimed invention, providing yet further innovations to advance the state of the art.

§ 3[b] "Research Preemption" Confusion in *Mayo* and *Alice*

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?

* * *

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)

The Supreme Court preoccupation with "preemption" in *Mayo* is discussed by Professor Lefstin:

[O]f the notions of "inventive concept" set forth in *Mayo*, preemption in fact is the least consonant with historical practice. Perhaps we ought not to care about historical practice, especially if we desire to write on a clean slate. But the Supreme Court clearly does. The Court regards the nineteenth-century English hot-blast cases, and its own nineteenth-century decisions such as *O'Reilly v. Morse*, as the fountainhead of the patent-eligibility doctrine. And of all the rationales the Court has invoked for excluding fundamental principles, the most consistent one is that the Court has been so doing for over 150 years.

Those nineteenth-century foundational cases clearly rejected the view that a patent could not effectively preempt all practical applications of a "principle," such as a newly discovered law of nature. In England, the famous hot-blast cases stood for the doctrine that a patent might preempt all uses of a newly discovered principle, provided that the patentee's disclosure was sufficient to enable application of the principle beyond his particular means. That was the consistent understanding in the United States as well. American courts always acknowledged the unpatentability of natural principles in the abstract, but assuming the patentee to have disclosed a means of application, did not inquire whether the patent would effectively preempt all uses of a natural law.

***

…*Mayo*—while justifying subject matter exclusions on grounds of preemption—suggests that policy concerns over preemption are analytically secondary to the test of exclusion. The *Mayo* Court declined to assess whether the patent in suit would actually preempt further innovation in the field, describing the possibility that the patent would "tie up too much future use of laws of nature" as an "underlying" concern, one that simply "reinforce[d]" the conclusion of patent-ineligibility. Likewise, the Court regarded

the prohibition against patenting fundamental principles as "a somewhat more easily administered proxy" for the underlying policy concerns. Thus, while *Mayo* grounded subject-matter exclusions in concerns over undue preemption, the Court's analysis indicates that preemption itself should not be the focus of step two.

The Court likely de-emphasized preemption because it foresaw that a test of preemption in fact would often be only a minor obstacle to patenting a principle. If *Mayo* step two permitted patenting of any non-preemptive application, then limiting a claim to a particular application of a principle would transform the claim into a patent-eligible application. That position was denied in *Bilski*'s gloss on *Flook*, where the Court held that limiting a claim to a particular technological environment or to one field of use could not by itself render an abstract idea patent-eligible. And indeed, for those post-*Alice* courts that have adopted a test of preemptive application, that contradiction has forced them to abandon preemption as a test when the patentee argues for the patent-eligibility of narrower dependent claims.

Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence Of Abstractions*, 16 N. C. J. L. & Tech. 647, 664-68 (2015)(footnotes omitted).

Mayo was followed 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:

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,* A*ssociation 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).

§ 3[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.).

In tune with *Deuterium* is the unequivocal and total denial in the Federal Circuit *Myriad* case of any third party right to use a patented invention; the opinion was issued by the now retired Vice President of SmithKline Beecham Corporation who has sat on the Federal Circuit since 1990: He unqualifiedly states that "during the term of the patent, unauthorized parties are 'preempted' from practicing the patent * * *." The *Myriad* case, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1331 (Fed. Cir. 2012)(Lourie, J.), *subsequent proceedings, Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013).

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.

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.)

More than a decade after *Deuterium* its author doubled down in the *Embrex* case where he ridiculed the experimental use defense: "[I]n my judgment, "the Patent Act leaves no room for any de minimis or experimental use *excuses* for infringement." *Embrex v. Service Eng'g Corp*., 216 F.3d 1343, 1352 (Fed.Cir.2000) (Rader, J., concurring)(emphasis added). The jurist added that "no room remains in the law for a de minimis *excuse*." *Id.* (emphasis added). Further, "this court has not tolerated the notion that a little infringement – de minimis infringement – is acceptable infringement or not infringement at all." *Embrex,* 216 F.3d 1352-53. "[T]he statute leaves no leeway to *excuse* infringement because the infringer only infringed a little." *Embrex,* 216 F.3d 1353 (emphasis added).

To do justice to the *Embrex* concurrence, it is useful to study the document itself to see precisely what it states:

"While joining the court's conclusions on all issues, I write separately because, in my judgment, the Patent Act leaves no room for any de minimis or experimental use excuses for infringement. Because the Patent Act confers the right to preclude 'use,' not 'substantial use,' no room remains in the law for a de minimis excuse. Similarly, because intent is irrelevant to patent infringement, an experimental use excuse cannot survive. When infringement is proven either minimal or wholly non-commercial, the damage computation process provides full flexibility for courts to preclude large (or perhaps any) awards for minimal infringements.

"I.

"This court affirms the district court's denial of SEC's de minimis and experimental use excuses, but I read the Patent Act to preclude these excuses altogether. SEC essentially asserts an affirmative defense, combining a plea based on the amount or quantum of infringing activity (de minimis) with a plea based on the character or intent of the infringing activity (experimental use). Although courts have occasionally addressed these separate excuses as if they were one, see, e.g., *Douglas v. United States*, 181 USPQ 170 (Ct. Cl. Trial Division 1974), *aff'd,* 510 F.2d 364 (1975), clarity calls for separate analyses.

"Since its inception, this court has not tolerated the notion that a little infringement – de minimis infringement – is acceptable infringement or not infringement at all. The statute states directly that any unauthorized use of a patented invention is an infringement. See 35 U.S.C. § 271(a) (1994). Thus, the statute leaves no leeway to excuse infringement because the infringer only infringed a little. Rather, the statute accommodates concerns about de minimis infringement in damages calculations. See *Deuterium Corp. v. United States,* 19 Cl. Ct. 624, 631 (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.'). Although not influencing the finding of infringement itself, the amount, quantum, or economic effect of wrongful conduct is central to the damages assessment. For these reasons, this court might better have declined SEC's invitation to engage in an inherently subjective determination of how little infringement is necessary to escape infringement liability. The Patent Act simply authorizes no such conjecture.

"II.

"Turning next to the experimental use excuse, neither the statute nor any past Supreme Court precedent gives any reason to excuse infringement because it was committed with a particular purpose or intent, such as for scientific experimentation or idle curiosity. Rather, the Supreme Court and this court have recently reiterated that intent is irrelevant to infringement. See *Warner-Jenkinson Co., v. Hilton Davis Chem. Co*., 520 U.S. 17, 34 (1997) ('Application of the doctrine of equivalents, therefore, is akin to determining literal infringement, and neither requires proof of intent.'); *Hilton Davis Chem. Co. v. Warner-Jenkinson Co*., 62 F.3d 1512, 1519 (Fed. Cir. 1995) ('Intent is not an element of infringement.'), *rev'd on other grounds*, 520 U.S. 17 (1997). These recent pronouncements should dispose of the intent-based prong of SEC's argument.

"Before *Warner-Jenkinson*, this court addressed arguments based on the character or intent of infringement in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.,* 733 F.2d 858, 863 (Fed. Cir. 1984); but see 35 U.S.C. § 271(e); *Glaxo, Inc. v. Novopharm, Ltd*., 110 F.3d 1562, 1568 (1997) (noting that § 271(e) changes the result in *Roche*). The Supreme Court's recent reiteration that infringement does not depend on the intent underlying the allegedly infringing conduct, to my eyes, precludes any further experimental use defense, even in the extraordinarily narrow form recognized in *Roche*. Of course, even if the experimental use excuse retains some lingering vitality, the

slightest commercial implication will render the 'philosophical inquiry/experimental use' doctrine inapplicable, as occurs in the court's resolution today."

Embrex, 216 F.3d at 1352-53 (Rader, J., concurring).

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).

To do justice to the *Madey* opinion, it is best to read what it says:

"The district court acknowledged a common law 'exception' for patent infringement liability for uses that, in the district court's words, are 'solely for research, academic or experimental purposes.' Summary Judgment Opinion at 9 (citing *Deuterium Corp. v. United States,* 19 Cl.Ct. 624, 631 (1990); *Whittemore v. Cutter,* 29 F. Cas. 1120 (C.C.D.Mass.1813) (No. 17,600); and citing two commentators[,. Janice M. Mueller, *No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools,* 76 Wash. L.Rev. 1, 17 (2001); 5 Chisum on Patents § 16.03[1] (2000)]).The district court recognized the debate over the scope of the experimental use defense, but cited this court's opinion in *Embrex, Inc. v. Service Engineering Corp.,* 216 F.3d 1343, 1349 (Fed.Cir. 2000) to hold that the defense was viable for experimental, non-profit purposes. *Summary Judgment Opinion* at 9 (citing *Embrex*[*, Inc. v. Service Engineering Corp.,* 216 F.3d 1343, 1349 (Fed.Cir. 2000)](noting that courts should not 'construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of `scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes laws in the guise of `scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes' (quoting *Roche Prods., Inc. v. Bolar Pharm. Co.,* 733 F.2d 858, 863 (Fed.Cir.1984))).

"After having recognized the experimental use defense, the district court then fashioned the defense for application to *Madey* in the passage set forth below.

"'Given this standard [for experimental use], for [*Madey*] to overcome his burden of establishing actionable infringement in this case, he must establish that [Duke] has not used the equipment at issue 'solely for an experimental or other non-profit purpose.' 5 Donald S. Chisum, *Chisum on Patents* § 16.03[1] (2000). More specifically, [Madey] must sufficiently establish that [Duke's] use of the patent had 'definite, cognizable, and not insubstantial commercial purposes.' *Roche Prods., Inc. v. Bolar Pharm. Co.,* 733 F.2d 858, 863 (Fed.Cir.1984)[ ]."

Madey v. Duke University, 307 F.3d 1351, 1355 (Fed. Cir. 2002)(Gajarsa, J.) footnote 2 integrated into text; footnote 3 omitted)

Note that *Madey* cites *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed.Cir.1984), for the denial of a right to experiment on a patented invention (whereas the case involved no experimentation *on* the invention but rather testing to gain regulatory approval). The superficial nature of the *Madey* opinion is its citation of Professor Janice M. Mueller, *No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L.Rev. 1 (2001), which clearly establishes a regime for dividing commercial exploitation from experimentation "on" the patented invention:

If the author of *Madey* actually read and understood Professor Mueller's piece, then the opinion in *Madey* could not possibly have turned out with such misunderstanding of the law.

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 specifications 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 in *Madey* may be likened to a case where there is a patented "microscope" and the accused infringement is the use of the microscope to study a subject – an *infringing* experimentation *with* the "microscope"; in contrast, studying the "microscope" itself, to, for example, improve the microscope or understand its operation, is a *noninfringing* experimentation *on* the patented "microscope".

The precise *factual* situation of an experimentation *on* a patented invention was raised in *Integra Life Sciences I,* but the accused infringer *waived* this argument 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.

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.)

§ 3[d] *Dueterium,* a Fantasyland Solution to a Real Problem

Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005), represents "Exhibit I" as to *why* there is a need for an experimental use right to experiment "on" a patented invention. At the trial level, Merck conducted experimentation "on" the patented invention, winning on some aspects at the trial level; but then Merck *abandoned* this defense at the Federal Circuit. Wegner, *Post*-Merck

Experimental Use and the "Safe Harbor," 15 Fed. Cir. B.J. 1, 3 (2005). Merck instead sought to judicially expand the scope of the "safe harbor" for regulatory approval testing of drugs under 35 USC § 271(e)(1) to deal with its classic experimental use of Integra's patent. Merck lost at the Federal Circuit but then won at the Supreme Court as the highest court judicially squeezed the truly experimental use by Merck into the safety of the regulatory approval testing exemption from infringement of Section 271(e)(1).

To mainstream patent academics it was preposterous to even think that there was no right to experiment on a patented invention. The Director of the Patent Law Program at George Washington University Law School as late as 2005 questioned the sanity of anyone who would deny the existence of a right to experiment on a patented invention, "a person who '[s]urely … needs the help of a mental health professional.'" Wegner, 15 Fed. Cir. B.J. at 8-9 (quoting 3 Martin J. Adelman *et al.*, PATENT LAW PERSPECTIVES § 3.6[2] at 3-78.2(3) (2nd ed. 2005)).

The failure of the Federal Circuit to rid itself of the *Deuterium* denial of a right to experiment on a patented invention makes absolutely no sense in the modern world of a new patent regime (where applications are *published* long before patents are granted, while the right to enforce the patent does not exist until the grant, permitting immediate testing and experimentation on the invention in this gap period of often several years). In the real world, parallel patent rights also do not start in foreign countries until patenting which is long after the mandatory publication of the patent application 18 months from the effective filing date.

Furthermore, enlightened foreign regimes permit experimentation "on" a patented invention even during the term of the patent: It makes no sense to have a *Deuterium* rule denying testing in the United States while there is no bar to overseas testing under parallel foreign laws. In fact, whereas *Deuterium* marked a virtual elimination of the right to experiment "on" a patented invention, other countries were moving in the direction of an even more liberal policy to permit experimentation on a patented invention as seen from the actions of the German Supreme Court in *Klinische Versuch I,* [1997] R.P.C. 623 (German Supreme Court), discussed in Wegner, 15 Fed. Cir. B.J. at 28-30. Japan has followed the same path as Germany. *Id.*, 15 Fed. Cir. B.J. at 30-33.

Given that experimentation "on" a patented invention is freely permitted throughout the term of a patent in Germany, Japan and elsewhere, it makes no sense for the United States to follow the *Deuterium* denial of an experimental use right. Should competitors in Europe and Asia be free to use patented technologies

to experiment to create new and better products when American competitors are blocked by the *Deuterium* denial of an experimental use right?

In fact, Americans today can benefit from the more liberal policies of Europe and Asia by sending their experimental work offshore and then importing the results of such testing into the United States. In *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367 (Fed. Cir., 2003), an unsuccessful attempt was made by a pharmaceutical patentee charging patent infringement where experimental tests were conducted in Germany and the results of such experimentation were put to practical use in the United States:

> This case presents questions concerning the interpretation of § 271(g), which provides:
>
> Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States *a product which is made by a process patented* in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.... A *product which is made by a patented process* will, for purposes of this title, not be considered to be so made after —
>
> (1) it is materially changed by subsequent processes; or
>
> (2) it becomes a trivial and nonessential component of another product.
>
> 35 U.S.C. § 271(g) (2000) (emphases added). We are concerned here in particular with the meaning of the phrase "a product which is made by a [patented] process." We have construed portions of this statute in a number of previous cases. *See, e.g., Mycogen Plant Sci., Inc. v. Monsanto Co.,* 252 F.3d 1306, 1318 (Fed.Cir.2001). ***
>
> ***
>
> The House report[,H.R.REP. No. 99-807,] reasoned that:
>
> "The failure of American patent law to make unlawful the *importation of goods made using an American process patent* has deep historical roots. American patent law — like the law of other nations — does not have an extraterritorial effect.... With respect to process patents, courts have reasoned that the only act of infringement is the act of making through the use of a patented process; therefore, there can be not infringement if that act occurs outside the United States. Although the courts are correctly construing current law, this rationale is inadequate public policy because it ignores the reality that the offending act is the importation of a product made through the use of a protected process patent or its subsequent sale within the United States."
>
> *Id.* at 5 (emphasis added). Here, the report equates products with physical "goods."

***

[The patentee]urges that section 271(g) was enacted "to provide protection to process patent owners which is *meaningful and not easily evaded.*" (Appellee's Br. at 15) (citing H.R.REP. No. 100-60 at 13). However, this broadly stated purpose hardly suggests that the statute covers information. ****

We, therefore, hold that in order for a product to have been "made by a process patented in the United States" it must have been a physical article that was "manufactured" and that the production of information is not covered.

Much more recently, Circuit Judge Newman has explained the real world situation that requires a *right* to experiment "on" a patented invention:

[T]he misperception that study of patented subject matter is precluded [by the patente right], has placed a misdirected spin on section 101.

The idea that experimentation with patented information is restricted is the basis of the view that patenting inhibits scientific advance. For example, the Court stated in *Mayo Collaborative Servs. v. Prometheus Labs., Inc*., 132 S.Ct. 1289 (2012), that "there 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."

However, the Court has recognized that "[t]he federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and unobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.,* 489 U.S. 141, 150–51(1989). See *J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc*., 534 U.S. 124, 142 (2001) ("The disclosure required by the Patent Act is 'the quid pro quo of the right to exclude.' "); *Kewanee Oil Co. v. Bicron Corp*., 416 U.S. 470, 484 (same).

This disclosure is available to produce further advance, on further study and experimentation. The Court long ago recognized that the scientific and technological information in patents may be studied, evaluated, tested, improved upon, compared, etc., as explained by Justice Story in *Whittemore v. Cutter*:

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

29 F. Cas. 1120, 1121 (C.C.D.Mass.1813). The Court reiterated this principle in *Graham v. John Deere Co.*, referring to the "inherent requisites in a patent system":

"Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'Promote the Progress of ... useful Arts.' This is the standard expressed in the Constitution and it may not be ignored."

383 U.S. 1, 6 (1966) (ellipses in original). The reference to "useful knowledge" cannot mean that the knowledge disclosed in patents is untouchable for seventeen years.

The Federal Circuit has reaffirmed that "patenting does not deprive the public of the right to experiment with and improve upon the patented subject matter." *In re Rosuvastatin Calcium Patent Litig.,* 703 F.3d 511*,* 527 (Fed.Cir.2012). However, in *Embrex, Inc. v. Service Engineering Corp*., 216 F.3d 1343, 1349 (Fed.Cir.2000), the court stated that the experimental use defense was "very narrow" and unavailable when "the inquiry has definite, cognizable, and not insubstantial commercial purpose," the concurrence adding that "neither the statute nor any past Supreme Court precedent gives any reason to excuse infringement because it was committed with a particular purpose or intent, such as for scientific experimentation," *id.* at 1353. Precedent does not support this theory.

The right to study and experiment, to evaluate and improve upon the information in patents was discussed by our predecessor Court of Claims in *Ordnance Engineering Corp. v. United States*, 84 Ct.Cl. 1 (1936) and in *Chesterfield v. United States*, 159 F.Supp. 371 (Ct.Cl.1958), the court explaining that experimentation does not infringe the patent. Factual distinctions may arise, as in *Pitcairn v. United States*, 212 Ct.Cl. 168 (Ct. Cl. 1976), where the Court of Claims held that of 2200 infringing helicopters, the use of 93 helicopters for testing or demonstration was not an "experimental use," as compared with the truly "experimental helicopters" that the patentee did not accuse of infringement.

Scholars have explained this essential policy of patent systems, whereby patented information adds to the body of knowledge, and the right to exclude does not prohibit further study of patented technology. *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use,* 56 U. Chi. L.Rev. 1017, 1022 (1989):

"If the public had absolutely no right to use the disclosure without the patent holder's consent until after the patent expired, it would make little sense to require that the disclosure be made freely available to the public at the outset of the patent term. The fact that the patent statute so plainly facilitates unauthorized uses of the invention while the patent is in effect suggests that some such uses are to be permitted."

See Janice M. Mueller, The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development, 56 Baylor L.Rev. 917, 921 (2004):

"The publication of information about a new invention in the form of an issued patent is of little use to society if that information is effectively kept 'on ice' for seventeen-eighteen years by means of a patent owner's unchecked right to exclude others from use for any purpose."

See also Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain,* 2004 Wis. L.Rev. 81 (2004) (distinguishing between infringing and non-infringing uses of information disclosed in patents, by differentiating between permissible "experimenting on" patented inventions, and impermissible "experimenting with" things that are patented); Andrew S. Baluch, *Relating the Two Experimental Uses in Patent Law: Inventor's Negation and Infringer's Defense,* 87 B.U. L.Rev. 213 (2007) (proposing that the right of experimental use by others balances the experimental use exception to § 102(b)).

Patents do not prevent experimentation with patented subject matter, whether the purpose is scientific knowledge or commercial potential. To hold otherwise would be to deny a foundation of the system of patents. However, the popular press has accepted the theory that experimentation is barred for patented subject matter, as have my colleagues, who cite that position as grounds for restricting eligibility under section 101.

The patent statute requires that the patented information is made known ("patent" is derived from the Latin "patere," which means "to lie open"), and that the patentee provide details of how to make and use the patented subject matter. In return, the patentee receives a term of exclusivity that has traditionally been applied only against commercial practice. On this simple bargain the industrial age blossomed, built on improvements and advances in patented subject matter.

Judicial precedent is sparse on the issue of experimental use, for until recently the principle was not in question. Technical publications often describe research in patent-heavy fields, apparently without fear of lawsuits. At a recent conference reported in the Patent, Trademark, & Copyright Journal, a spokesman stated that "research has been spurred rather than inhibited as a result of the [Myriad] patents, citing 18,000 researchers who have published over 10,000 articles...." 85 PTCJ 759 (2013).

In summary, *experimental* use of patented information can take various forms, including:

a. *experiments to improve or build upon patented subject matter*— such studies are encouraged by the patent system; it has never been the law that such experimentation is infringement.

b. *experiments to compare patented subject matter with alternatives to determine relative performance and properties*— Improvements would be inhibited if new developments could not be compared with the old. Such a position has never been the law.

c. *experimental study of patented subject matter to understand its mechanism*— Such scientific study is an important attribute of patent systems. Scientific understanding may or may not lead to new commercial embodiments, which are not excused from infringement if covered by valid claims; but study of patented subject matter is not infringement.

d. *experimental study of patented subject matter to find new applications or modifications*— Such new directions are a benefit of the patent system; the experimentation is not infringement.

The courts, the press, and the public, have been led down a path that is contrary to patent principles. Let us remove the doubts we have sown. With clarification of the right to experiment with the information disclosed in patents, it will no longer be necessary to resort to the gambit of treating such information as an "abstraction" in order to liberate the subject matter for experimentation, whether for scientific or commercial purposes. ***

CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1322-25 (Fed. Cir. 2013)(en banc)(per curiam)(Newman, J., dissenting in part), *subsequent proceedings sub nom Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014)(footnotes omitted or integrated into text in brackets)

§ 3[e] Experimentation "On" Technology: The Industry Norm

Experimentation "on" patented technology is widespread and the norm and runs counter to the *Deuterium* proscription on experimental use. The pharmaceutical industry is a prime example. Since the establishment of the modern organic chemistry on the Rhine it has been commonplace to experiment on patented inventions. Thus has long been the case and standard practice of major American pharmaceutical companies to *routinely* study recently patented inventions, to experiment on the latest patented molecules to see how they operate, to compare them to the state of the art and to use such patented molecules for research to make new and better drugs.

Yet, the former Vice-President of one of the largest pharmaceutical houses in the world in his current role as a jurist says that there is complete patent preemption without leaving room for a right to experiment on a patented invention. *See* the *Myriad* case, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1331 (Fed. Cir. 2012)(Lourie, J.), *subsequent proceedings, Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013)("[A] limited preemption is inherent in every patent: the right to exclude for a limited period of time. *** When the patent expires, the public is entitled to practice the invention of the patent. That is true of all inventions; *during the term of the patent, unauthorized parties are 'preempted' from practicing the patent,* but only for its limited term.")(citation omitted; emphasis added).

♦ ♦ ♦

§ 4. PATENT-ELIGIBILITY OF THE *CLAIMED* INVENTION

The *Sequenom* case presents the most severe patent-eligibility challenge now on the horizon: Claim 1 of the Sequenom patent requires a combination of three distinct steps:

1. A method for detecting a paternally inherited nucleic acid of fetal origin [a] *performed on a maternal serum or plasma sample* from a pregnant female, which method comprises
[b] *amplifying a paternally inherited nucleic acid* from the serum or plasma sample and
[c] *detecting the presence of a paternally inherited nucleic acid* of fetal origin in the sample." [emphasis added]

The claim is to clearly "inventive" subject matter, particularly as the three steps in "ordered combination" are nowhere suggested in the prior art:

First, in an invasive procedure, serum or plasma taken from the mother's womb must be obtained, as the claimed invention expressly excludes a test from a blood sample taken from the arm as in any traditional blood test: The test is "performed on a maternal serum or plasma sample from a pregnant female[.]" Sequenom claim 1.

Second, because there is *de minimis* amount of paternally inherited DNA in the sample taken from the womb, it is necessary to "amplify[ ] a paternally inherited nucleic acid from the serum or plasma sample[.]" *Id.*

Third, the claim finally requires use of the thus-amplified sample to "detecting the presence of a paternally inherited nucleic acid of fetal origin ***." *Id.*

It is the ordered combination of all three features which makes up claim 1: There is infringement of the Sequenom patent only when *all three* features are found in combination. While the second element of amplification (with polymerase chain reaction) was relatively new, in the context of the 1997 invention date of the Sequenom patent, it had already been fourteen (14) years since Dr. Cary Mullis had received his Nobel Prize for this amazing discovery. Thus, the polymerase chain reaction was not some obscure technology but one extremely familiar to everyone skilled in the art for the fourteen (14) year between the Nobel Prize award and the invention date of the Sequenom patent.

It is beyond question that the Sequenom *recognition* that there is a minute quantity of the desired DNA in a womb sample in combination with the polymerase chain reaction is far away from the "apply it" line of case law: The ordered combination of the Sequenom claim was indeed a pioneer invention, to permit genetic testing through simply drawing blood from the arm of the mother instead of a womb-invasive sampling of bodily fluid. Such a pioneer invention is clearly nonobvious, i.e., "inventive" in the sense of the *Mayo/Alice* analysis.

Circuit Judge Chen explains the *Mayo/Alice* analysis in *DDR Holdings, LLC v. Hotels.Com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014)(Chen, J.); and *Content Extraction and Transmission LLC v. Wells Fargo Bank*, 776 F.3d 1343 (Fed. Cir., 2014)(Chen, J.). In both cases he points out that the *Mayo/Alice* analysis asks whether there is "an ordered combination" that has an "inventive concept", the presence of which puts the subject matter in the category of patent-eligibility under 35 USC § 101.

In *DDR Holdings*, the court points out that "we determine whether the claims at issue are directed to a patent-ineligible abstract idea. *Alice Corp. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2355 (2014). If so, we then 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 of that abstract idea. *Id.* This second step is the search for an 'inventive concept,' or some element or *combination of elements* sufficient to ensure that the claim in practice amounts to 'significantly more' than a patent on an ineligible concept. *Id." DDR Holdings*, 773 F.3d at 1255 (emphasis added).

In *Content Extraction* the court reiterates that "[t]he Supreme Court's two-step framework, described in *Mayo* and *Alice*, guides our analysis. *Alice* [*Corp. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2355 (2014)] (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1296–97 (2012)). We first determine whether a claim is 'directed to' a patent-ineligible abstract idea. If so, we then consider the elements of the claim—both individually and *as an ordered combination* —to assess whether the additional elements transform the nature of the claim into a patent-eligible application of the abstract idea. *Id.* This is the search for an 'inventive concept'—something sufficient to ensure that the claim amounts to 'significantly more' than the abstract idea itself. *Id.*" *Content Extraction*, 776 F.3d at 1346-47 (emphasis added).

§ 4[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. 39, 48-49 (1966).

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, 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.

§ 4[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 (as carried forward in the *Leahy Smith America Invents Act* of 2011) – 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.
>
> 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).

§ 4[c] The *Alice* Restatement of *Mayo* Patent-Eligibility Exclusions

The Federal Circuit in the *Ariosa* case speaks of the "*Mayo*/*Alice* framework" for determination of patent-eligibility, referencing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.,* 132 S. Ct. 1289 (2012), and *Alice Corp. Pty. Ltd. v. CLS Bank Int'l,* 134 S.Ct. 2347 (2014). . *See* § 9[a][2], *The Dyk Concurrence with Denial of Rehearing En Banc* (quoting the concurrence of Judge Dyk in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __ (Fed. Cir. Dec. 2, 2015), *panel proceedings,* 788 F.3d 1371 (Fed. Cir. 2015), describing the *Mayo*/*Alice* framework in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __ (Fed. Cir. Dec. 2, 2015)(Order den. reh'g en banc)).

In the context of the *Sequenom* case, it is useful to have a more complete understanding of what the court has set forth in the second of the two cases, *Alice Corp. Pty. Ltd. v. CLS Bank Int'l,* 134 S.Ct. 2347 (2014)(Thomas, J.). (For a deeper understanding of the "*Mayo/Alice*" problem, it is also useful to study the *Mayo* case, which is explored at § 3[b], **"***Research Preemption" Confusion in Mayo*). As explained by Justice Thomas in *Alice:*

: "We have described the concern that drives th[e] exclusionary principle [denying patent-eligibility to certain areas 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* [citation omitted]. '[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* [citation omitted]); 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* [citation omitted](citing [*O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 113 (1854)]).

"At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. *Mayo* [citation omitted]).. At some level, 'all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.' *Mayo* [citation omitted]. Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept. See *Diamond* v. *Diehr,* 450 U. S. 175, 187 (1981). '[A]pplication[s]' of such concepts ' 'to a new and useful end,' ' we have said, remain eligible for patent protection. *Gottschalk* v. *Benson,* 409 U. S. 63, 67 (1972). Accordingly, in 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* [citation omitted], thereby 'transform[ing]'

them into a patent-eligible invention, *Mayo* [citation omitted]. The former 'would risk disproportionately tying up the use of the underlying' ideas, *Mayo* [citation omitted], 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.

III

"In *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.,* 566 U. S. ___ (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. *Mayo* [citation omitted]. If so, we then ask, '[w]hat else is there in the claims before us?' *Mayo* [citation omitted]. 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. *Id.,* at ___ (slip op., at 10, 9). 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.' *Id.,* at ___ (slip op., at 3).[3]

A

We must first determine whether the claims at issue are directed to a patent-ineligible concept. We conclude that they are: These claims are drawn to the abstract idea of intermediated settlement.

The 'abstract ideas' category embodies 'the longstanding rule that '[a]n idea of itself is not patentable.' ' *Ben*son, *supra,* at 67 (quoting *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498, 507 (1874); *see also Le Roy* [*v. Tatham,* 55 U.S. (14 How.) 156, 175 (1853)] ('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 '). In *Benson,* for example, this Court rejected as ineligible patent claims involving an algorithm for converting binary-coded decimal numerals into pure binary form, holding that the claimed patent was 'in practical effect . . . a patent on the algorithm itself.' 409 U. S., at 71-72. And in *Parker* v. *Flook,* 437 U. S. 584, 594-95 (1978), we held that a mathematical formula for computing 'alarm limits' in a catalytic conversion process was also a patent-ineligible abstract idea.

* * *

'[A]ll members of the Court agree[d]' that the patent at issue in *Bilski* claimed an 'abstract idea.' [*Bilski v. Kappos,* 561 U. S. 593, 609 (2010)(Stevens, J., concurring in judgment). Specifically, the claims described 'the basic concept of hedging, or protecting against risk.' *Id.,* at 611. The Court explained that ' '[h]edging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class.' ' *Ibid.* 'The concept of hedging' as recited by the claims

in suit was therefore a patent-ineligible 'abstract idea, just like the algorithms at issue in *Benson* and *Flook.' Ibid.*

* * *

B

Because the claims at issue are directed to the abstract idea ***, we turn to the second step in *Mayo*'s framework. ***

1

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. [citation omitted]. 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].' *Id.* citation omitted]. *Mayo* made clear that transformation into a patent-eligible application requires 'more than simply stat[ing] the [abstract idea] while adding the words 'apply it.' [citation omitted]

§ 4[c][1] *Morse* Concern over "Preemption"

Justice Thomas in *Alice* explains that it is "preemption" of future innovation that is the basis for the exclusions to patent-eligibility under 35 USC §101:

"We have described the concern that drives th[e] exclusionary principle [denying patent-eligibility to certain areas 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* [citation omitted].

'[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* [citation omitted]); 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* [citation omitted]*Mayo* [citation omitted](citing [*O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 113 (1854)]).

§ 4[c][1][A] Patents do not "Preempt" Research

It is well settled that nineteenth century case law established the right to experiment "on" a patented invention: The public historically has had a *right* to experiment on a patented invention so the concept of a patent "research preemption" in the context of classic case law is mythology. *See* § 3**,** *Alice Mythology of a Research "Preemption".*

Permitting research "on" a patented invention is consistent with the Constitutional objective "to Promote the Progress of *** thee Useful Arts". *See* § 3[a], *Constitutional Right To Experiment on a Patented Invention.* The *right* to experiment "on" a patented invention dates back to the earliest days of the Nation. *See* **§** 3[a][1], *The Story Line of Case Law*, citing *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) (Story, J.)(riding circuit); *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391) (Story, J., riding circuit); *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617, 626 (2008); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917).

Ancillary to the false idea that patents block research, recent cases have expressed concern that a "broad" patent may hinder research. *See* § 2[b][1], *"Too Much" Patent Protection vs. Real World Realities* (discussing *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126 (2006) (Breyer, J., joined by Stevens, Souter, JJ., dissenting from dismissal of writ of certiorari)(arguing that "*too much* patent protection can impede rather than `promote the Progress of Science and useful Arts[.]'") This view runs directly in contrast to the foundational case law establishing that a pioneer invention should be given *broader* protection beyond the literal patent grant. *See* § 3[a][2], *Broad Patents "Promote the Progress of *** the Useful Arts," See also* . § 2[b][2], *Early Supreme Court Recognition of the Need forBroad Protection* (citing *Morley Sewing-Machine Co. v. Lancaster*, 129 U. S. 263 (1889); *Miller v. Eagle Mfg. Co.*, 151 U. S. 186 (1894); *Cimiotti Unhairing Co. v. American Fur Refining Co.*, 198 U.S. 399 (1905); *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 (1908)).

If there is any problem with this basic concept that broad patents do not preempt research and indeed pioneer patents should be broadly interpreted, the fault lies not with the Supreme Court but with the muddled state of the case law at the Federal Circuit inspired by its recently resigned Chief Judge. *See* § 3[c],

Deuterium Ghost at the Federal Circuit (discussing *Deuterium Corp. v. United States*, 19 Cl.Ct. 624 (Cl.Ct.1990)(Rader, J.)(denying the existence of a right to experiment on a patented invention by 'question[ing] whether any infringing use can be de minimis.'") .

§ 4[c][1][B] An "Inventive" Application is Patent-Eligible

In *Alice* (more fully quoted earlier in this chapter) the Court outlines the *Mayo* analysis to determine when a claim that includes a patent-ineligible element precisely how patent-eligibility for the claimed invention is determined. Included within the quotation from *Alice* is the following admonition for determining patent-eligibility where one element lacks patent-eligibility: "[W]e consider the elements of each claim *** 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application. We have described [this] step two of this analysis as a search for an ' 'inventive concept' '—*i.e.*, *** [a] 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.'" [citations omitted]

Continuing further down in *Alice*, the Court explains that "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. 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].' *Mayo* made clear that transformation into a patent-eligible application requires 'more than simply stat[ing] the [abstract idea] while adding the words 'apply it.'" [citations omitted].

§ 4[c][1][C] Identifying a Natural Product does not Preempt its Use

It is fundamental that preemption of the *use* of an element that lacks patent-eligibility is at the very core of the "preemption" argument against patent-eligibility. Thus, if one has a patented electron microscope that identifies a particular natural structure, the electron microscope is not suddenly lacking in patent-eligibility simply because one element of the patented electron microscope is used in a process for *identifying* a natural product. So, too, is there no preemption of naturally occurring DNA where the claimed process is to *identify* the DNA. The DNA, before its analysis or after, is the same DNA. It is not patentable as a product of nature. A claim to a method of identifying that DNA

simply has no preclusive effect on the use of that DNA: The claim is only to one way of identifying the DNA.

The classic case where this concept is not understood is *Sequenom v. Ariosa Diagnostics*, the styling of the likely early 2016 petition for *certiorari* from *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __ (Fed. Cir. Dec. 2, 2015), *panel proceedings*, 788 F.3d 1371 (Fed. Cir. 2015). In that case the patent claims a method to *identify* DNA and claims neither DNA nor its use as explained in Chapter 9, *The Sequenom Petition for Certiorari.*

♦ ♦ ♦

§ 5. PATENT ELIGIBILITY AND PATENTABILITY CONFLATION

§ 5[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 – possessed "invention", or an "inventive" feature; the law developed through cases beginning in the mid-nineteenth century, finally to be codified in the 1952 Patent Act as 35 USC § 103 (and now carried forward in the *Leahy Smith America Invents Act* of 2011). This common understanding was shattered by Supreme Court decisions in *Gottschalk* v. *Benson*, 409 U.S. 63 (1972); and *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).

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 kiss 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. ***

§ 5[b] **"Inventive" Subject Matter Prior to the 1952 Patent Act**

In the context of the 1952 Patent Act, carried forward in the *Leahy Smith America Invents Act* of 2011, 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 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 Systeems, 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 F.2d 609, 616 (6th Cir.1974)(The witness Ketchum testified … [as to] 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 (and carried forward in the *Leahy Smith America Invents Act* of 2011):

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_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).

§ 5[c] "Inventive" Quality beyond Nonobviousness

It should be noted that Professor Lefstin takes a different view as to the meaning of "inventive" in the context of patent-eligibility which the reader should consider and gauge for himself. Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence of Abstractions*, 16 N. C. J. L. & Tech. 647 (2015). Despite the persuasive work of Prof. Lefstin, this writer remains of the view that when the Supreme Court speaks of an application being "inventive" this should mean a nonobvious modification under 35 USC §103. In fact, it is this writer's opinion that a differentiation over an abstract principle that is less than "inventive" or "nonobvious" should, in theory, not be outcome determinative as to patent-*eligibility*. But, since an invention must be *patentable* as well as patent-*eligible*, this is a distinction not worth the practical effort to pursue: If an invention is obvious, it is not patentable – whether patent-eligible or not.

§ 6. 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*).

§ 6[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 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).

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, 106 S.Ct. 1578, 89 L.Ed.2d 817 (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).

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. 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(quoting *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 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).

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).

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

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 *patentability* question open as 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 should 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 is *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2352 (2014).

§ 6[b] **The Current Bilski Era (2010 - ____)**

Alice explains the *Benson* case in terms of "inventive concept": "Patent-eligibility in [*Gottschalk* v. *Benson*, 409 U.S. 63 (1972),] 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 *Benson*, 409 U.S. at 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).

§ 6[b][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*.)

§ 6[b][2] The Rigid *Mayo* "Apply It" Test

§ 6[b][2][A] An Improper *Per Se* Denial of Patentability

Combination claims that combine a traditional element and a software element have frequently been denied patent-eligibility through a dissection of the claim to expose the software element that, standing alone, lacks patent-eligibility.

There have been several "apply it" cases to claims where an otherwise conventional process is claimed in combination with a generic application of computer software, simply a combination of the conventional process plus instructions to "apply it" with software. A substantial number of opinions from both the Supreme Court and Federal Circuit have denied such claims on the basis of a denial of patent-eligibility under 35 USC §101.

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."); *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 recent example is the statement by the Supreme Court in *Alice* that "the mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention. Stating an abstract idea 'while adding the words 'apply it' ' is not enough for patent eligibility." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S.Ct. 2347, ___ (2014)(citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)).

Earlier, the Court in *Mayo* explained that "to transform an unpatentable law of nature into a patent-eligible application of such a law, a patent must do more than simply state the law of nature while adding the words 'apply it.'" *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) (citing *Gottschalk* v. *Benson*, 409 U. S. 63, 71-72 (1972)).

The Federal Circuit has unfortunately often chosen to echo the Supreme Court "apply it" line of case law: The Chief Judge in *CLS Bank* explained: "The claim in effect presents an abstract idea and then says 'apply it.' That is not enough. [*Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012)]('[T]o transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'')". *CLS Bank Int'l v. Alice Corp.*, 685 F.3d 1341, 1358 (Fed. Cir. 2012)(Prost, J., dissenting), *vacated*, 717 F.3d 1269, 1277 (Fed. Cir., 2013)(en banc)(per curiam), *subsequent proceedings, Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S.Ct. 2347 (2014).

In *Ariosa* the majority opinion explained:

"Mayo [*Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012),] made clear that transformation into a patent-eligible application requires 'more than simply stat[ing] the law of nature while adding the words 'apply it.'' *Id*. at 1294. A claim that recites an abstract idea, law of nature, or natural phenomenon must include 'additional features' to ensure 'that the [claim] is more than a drafting effort designed to monopolize the [abstract idea, law of nature, or natural phenomenon].' *Id*. at 1297. For process claims that encompass natural phenomenon, the process steps are the additional features that must be new and useful. *See Parker v. Flook*, 437 U.S. 584, 591 (1978) ('The process itself, not merely the mathematical algorithm, must be new and useful.')."

Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, ___ (Fed. Cir. 2015). (Reyna, J.)

In *Versata v. SAP,* the court explained:

"[T]he Supreme Court has identified a two-step framework [in its patent-eligibility analysis]. First, determine whether the claims at issue are directed to one of the patent-ineligible concepts. [*Alice Corp. Pty. Ltd. v. CLS Bank Int'l,* 134 S.Ct. 2347, 2355 (2014)]; *see also Mayo Collaborative Servs*. *v*. *Prometheus Labs*., *Inc*., 132 S. Ct. 1289, 1296-97 (2012) (setting forth the same two-step framework). Second, if the claims are directed to patent-ineligible subject matter, ask ''[w]hat else is there in the claims before us?'' *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 132 S. Ct. at 1297).

"To answer the second question, we consider the limitations of each claim both individually and as an ordered combination to determine whether the additional limitations transform the nature of the claim into a patent-eligible application of a patent-ineligible concept. *Id*. The Supreme Court has described this second step as a search for an inventive concept – a limitation or combination of limitations that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon an ineligible concept itself. *Id*.

"In other words, 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. *Id*. at 2357. 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. Similarly, the prohibition on patenting an ineligible concept cannot be circumvented by limiting the use of an ineligible concept to a particular technological environment. *Id*."

Versata Dev. Grp., Inc. v. SAP Am., Inc., __ F.3d __-(Fed. Cir. 2015)(Plager, J.).

Circuit Judge Bryson explained in the *Myriad* case that:

"In [*Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)], the Supreme Court invalidated claims directed to the relationship between concentrations of certain metabolites in the blood and the likelihood that a particular dosage of a thiopurine drug will be optimum, stating that steps of 'administering' and 'determining,'

coupled with a correlative 'wherein' clause, were insufficient to differentiate the claimed method from the natural laws encompassed by the claims. In short, 'to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words 'apply it'.' 132 S.Ct. at 1294."

The *Myriad* Case, *The Ass'n For Molecular Pathology v. U.S. Patent and Trademark Office* , 653 F.3d 1329, 1379-80 (Fed. Cir., 2011)(Bryson, J., concurring in part and dissenting in part), *vacated, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012)(en banc), *subsequent proceedings sub nom Association for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013).

Judge Lourie in *Accenture Global* explains that)"[t]he system claims are [akin] to stating the abstract idea [of the method claim] . . . and adding the words: 'apply it' on a computer." *Accenture Global Servs., GmbH v. Guidewire Software, Inc.*, __ F.3d __, __ (Fed. Cir. 2013)(Lourie, J.) (quoting *CLS Bank*, 717 F.3d at 1291 (plurality opinion), citing *Mayo*, 132 S. Ct. at 1294).

Judge Lourie in *Ultramercial* explains that:

"We must examine the limitations of the claims to determine whether the claims contain an 'inventive concept' to 'transform' the claimed abstract idea into patent-eligible subject matter. *Alice,* 134 S.Ct. at 2357 (quoting *Mayo* [*Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294, 1298 (2012)]. The transformation of an abstract idea into patent-eligible subject matter 'requires more than simply stat[ing] the [abstract idea] while adding the words 'apply it.' ' *Id.* (quoting *Mayo,* 132 S.Ct. at 1294) (alterations in original). '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].' ' *Id.* (quoting *Mayo,* 132 S.Ct. at 1297) (alterations in original). Those 'additional features' must be more than 'well-understood, routine, conventional activity.' *Mayo,* 132 S.Ct. at 1298."

Ultramercial, Inc. v. Hulu, LLC, 772 F.3d 709, 715 (Fed. Cir. 2014)(Lourie, J.).

Judge Dyk explains that:

"If we determine that the patent is drawn to an abstract idea or otherwise ineligible subject matter, at a second step we ask whether the remaining elements, either in isolation or combination with the non-patent-ineligible elements, are sufficient to ''transform the nature of the claim' into a patent-eligible application.' *Alice* [*Corp. Pty. Ltd. v. CLS Bank Int'l,* 134 S.Ct. 2347, 2358 (2014)] (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297 (2012)). Put another way, there must be an 'inventive concept' to take the claim into the realm of patent-eligibility. *Id*. at 2355.

A simple instruction to apply an abstract idea on a computer is not enough. *Alice*, 134 S. Ct. 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))."

Intellectual Ventures I LLC v. Capital One Bank, __ F.3d __, __ (Fed. Cir., 2015)(Dyk, J.)

§ 6[b][2][B] "Apply It" Claims Denied Patent-Eligibility

It is manifestly improper to deny claims to a *combination* of a traditional element and an element that, standing alone, lacks patent-eligibility. The "apply it" line of case law has denied claims on the basis of a lack of patent-eligibility under 35 USC §101, whereas, more properly, the claims should have been denied on the basis that to "apply" generic software as part of a combination is *obvious* under 35 USC §103. So, if the invention is obvious, what's the difference whether the standard is patent-eligibility under Section 101 or obviousness under Section 103?

The "apply it" statements in the first instance are unfortunate in that the Court reaches a conclusion denying patent-eligibility under 35 USC §101 when in fact the correct statutory basis should be that the claimed combination of generic software and a second feature is *obvious* under 35 USC § 103. The Federal Circuit has abdicated its responsibility to present a rational view of patent case law in a series of decisions which for the most part merely parrot the "apply it" language of the Supreme Court, implicitly reinforcing the idea that one may dissect a claim to a combination and reach a conclusion of lack of patent-eligibility because one of the elements, standing alone, lacks patent-eligibility.

Why does it matter that a patent is held invalid for lack of patent-eligibility under Section 101 when it should have been held invalid under Section 103 as directed to an obvious variation of the prior art?

The answer is that the Court takes a short cut to simply deny patenting of inventions that *could* be considered nonobvious if properly under the microscope of Section 103: "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." *See* § 6[a], *The Fact-Intensive Four Factor Graham Test* (quoting *In re Lockwood*, 50 F.3d 966, 970 n.4 (Fed. Cir.

1995)(citing *Graham v. John Deere Co.*, 383 U.S. 1 (1966), and quoting *Specialty Composites v. Cabot Corp*., 845 F.2d 981, 989 (Fed.Cir.1988)).

Perhaps the state of the art *teaches away* from using software in connection with a particular conventional element, and on that basis the claims should be granted. See *In re Mouttet*, 686 F.3d 1322, 1333 (Fed. Cir. 2012)(Reyna, J.)(citing *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc*., 567 F.3d 1314, 1326–27 (Fed.Cir.2009))("A reference that properly teaches away can preclude a determination that the reference renders a claim obvious." As stated in *KSR:* "[W]hen the prior art *teaches away* from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007)(citing *United States v. Adams*, 383 U.S. 39, 51-52 (1966))(emphasis added)

In some situations a combination of prior art references is needed to establish obviousness of claim to a combination of elements, a sometimes complex matter that may implicate factors such as demands known to the design community or the background knowledge of those skilled in the art:

The patent applicant or patentee should be allowed to introduce evidence to show that the prior art teaches away from the claimed invention: "[W]hen the prior art *teaches away* from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007)(citing *United States v. Adams*, 383 U.S. 39, 51-52 (1966))(emphasis added)

"Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR v. Teleflex*, 550 U.S. at 418.

Furthermore, as a factual issue, the patent applicant or patentee should be able to produce evidence showing that the prior art teaches away from the claimed invention. *Mouttet*, 686 F.3d at 1333 (Fed. Cir. 2012)(Reyna, J.)(citing See *In re Napier*, 55 F.3d 610, 613 (Fed.Cir.1995))(" Whether or not a reference teaches away from a claimed invention is a question of fact.")

§ 6[b][3] ***Alice, Mayo Déjà vu***

In terms of the search for "inventive" subject matter *Alice r*eprises 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:*

"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).

§ 6[b][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).

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.

§ 7. 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.

§ 7[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 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) ("[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).

As to the difference between the Chakrabarty invention and the prior art there was *no issue* raised by the Patent Office challenging the presence of "invention" (or nonobviousness), which is perhaps best appreciated by a study of the appellate court decision where nonobviousness was *unquestioned*:

"The PTO has raised no issue *** about compliance with the 'conditions and requirements of this title,' that is to say the basic Title 35 requirements for patentability, which are utility, novelty, and nonobviousness (35 U.S.C. §§ 101, 102, and 103) ***. The sole issue, as the PTO chooses to view it, is whether an invention, otherwise patentable under the statute, is excluded from the categories of subject matter which may be patented, set forth in § 101, because it is 'alive.' ***." *In re Bergy,* 596 F.2d 952, 956 (CCPA 1979)(Rich, J.), ***aff'd as to Chakrabarty sub nom Diamond v. Chakrabarty,*** 447 U.S. 303 (1980).

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 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)

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[*] 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 [*In re Papesch*, 315 F.2d 381 (CCPA 1963)]. *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).")

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. It 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).

In the *Myriad* case at the Supreme Court, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc*., 133 S. Ct. 2107, 2117 (2013), the Court referenced the Chakrabarty invention of newly created structures that were held to represent statutory subject matter: "The Chakrabarty bacterium was new 'with *markedly different* characteristics from any found in nature,' [*Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)], 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." (emphasis added).

Reference to the "markedly different" characteristics is found once again in *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1336 (Fed. Cir. 2014)(Dyk, J.).

"In [*Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)], the Court clarified the scope of [*Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948)]. The patent at issue in *Chakrabarty* claimed a genetically engineered bacterium that was capable of breaking down various components of crude oil. 447 U.S. at 305. The patent applicant created this non-naturally occurring bacterium by adding four plasmids to a specific strain of bacteria. Id., at 305 n. 1. Overturning the Board's rejections, the Court held that the modified bacterium was patentable because it was 'new' with ' markedly different characteristics from any found in nature and one having the potential for significant utility.' *Id*. at 310. As the Court explained, the patentee's 'discovery is not nature's handiwork, but his own.' Id.

"Accordingly, discoveries that possess 'markedly different characteristics from any found in nature,' *id*., are eligible for patent protection. In contrast, any existing organism or newly discovered plant found in the wild is not patentable. *Id.* at 309; see also *In re Beineke*, 690 F.3d 1344, 1352 (Fed.Cir.2012) (holding that a newly discovered type of plant is not eligible for plant patent protection, in part, because such a plant was not 'in any way the result of [the patent applicant's] creative efforts or indeed anyone's creative efforts.')."

§ 7[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." [*]

[*] Claim 31, rewritten in independent form:

§ 7[c] ***Funk v. Kalo* "Nature's Secrets" Dicta**

***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*, 67 Fla. L. Rev. 565 (2015); *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."

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 …

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 innoculated medium of claim 30 wherein the carrier medium is straw."

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).

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."

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.

§ 7[d] ***Myriad* Characterization of *Chakrabarty***

More than thirty years removed from *Chakrabarty* the issue 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).

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).

§ 7[d][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.

§ 7[d][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.

§ 7[d][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.

§ 7[d][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.))

§ 7[d][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 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, 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.

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§ 8. ISSUES OF IMPORTANCE IN *SEQUENOM*

The *Sequenom* case is a patent piñata having a host of issues. The extreme nature of the case is explained in the concurring opinion by the elder member of the panel in *Ariosa*:

"*** 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 *Household 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).

The *Ariosa* majority opinion is flawed in its understanding of Supreme Court case law:

In the first instance, *Ariosa* fails to consider patent-eligibility for the *claimed* invention *as a whole* under the "all elements" rule; the majority fails to consider the limitations on the scope of the *Flook* case that were made in the subsequent opinion in *Diamond v. Diehr*. *See* § 8[b][1], *Flook versus the "All Elements" Rule.*

In the second instance, the majority selectively quotes from *Mayo* focusing upon the denial of patent-eligibility where a computer element is added – to "apply it" – while excluding from its quotation the sentence immediately following "apply it" where the Court notes the patent-eligibility of subject matter where the claimed combination is an "inventive application." *See* § 8[a][4], *Ariosa Mischaracterization of Mayo*

There are at least three important issues within the *Ariosa* opinion that are worthy of reconsideration:

§ 8[a] "Inventive" Subject Matter Lacking Patent-Eligibility

§ 8[a][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* 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.

§ 8[a][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 __.

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 lof 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:

"*** 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 MateriT21 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 *Household 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).

§ 8[a][3] Intra-Circuit Split over Scope of Patent Eligibility

The Federal Circuit has yet to provide a uniform answer to the following issue:

If there is "inventive" subject matter – subject matter that is thus "nonobvious" under 35 USC § 103, 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).

§ 8[a][4] *Ariosa* Mischaracterization of *Mayo*

The majority opinion in *Ariosa* mischaracterizes *Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 132 S. Ct. 1289 (2012), through the tool of an edited quotation that omits a key point. Thus, the *Ariosa* majority states:

> "*Mayo* made clear that transformation into a patent-eligible application requires '*more than simply stat[ing] the law of nature while adding the words 'apply it.'' Id.* at 1294. A claim that recites an abstract idea, law of nature, or natural phenomenon must include 'additional features' to ensure 'that the [claim] is more than a drafting effort designed to monopolize the [abstract idea, law of nature, or natural phenomenon].' *Id*. at 1297. For process claims that encompass natural phenomenon, the process steps are the additional features that must be new and useful. *See Parker v. Flook*, 437 U.S. 584, 591 (1978) ('The process itself, not merely the mathematical algorithm, must be new and useful.')."

Ariosa, __ F.3d at ___ (Reyna, majority opinion).

Clearly, if it is *obvious* to transform a previous process to a computer-implemented process, then a generic recitation including software – to "apply it" – does not create an unobvious invention. But, if the claimed invention *as a whole* includes features which in combination are not obvious, then the "apply it" logic stated in the quotation from *Mayo* does not apply. This is clear from *Mayo* itself

where the Court in the very next sentence after the "apply it" quotation states that to be patent-eligible, the claim "must limit its reach to a particular, inventive application of the law." Mayo, 132 S. Ct. at 1294; emphasis added.

To be sure, *Mayo* is not the last word from the Supreme Court on the matter of the patent-eligibility of "inventive" subject matter: But, *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014), if anything, supports the view that an "inventive" application of an abstract concept is patent-eligible: "[W]e consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application. We have described step two of this analysis as *a search for an ' 'inventive concept' '—i.e.,* an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'" *Alice*, __ U.S. at __ (emphasis added; citations and footnote omitted). *See also Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 715 (Fed. Cir., 2014)(Lourie, J.)(citing *Alice*, 134 S.Ct. at 2357, quoting *Mayo*, 132 S.Ct. at 1294, 1298)("We must examine the limitations of the claims to determine whether the claims contain an 'inventive concept' to 'transform' the claimed abstract idea into patent-eligible subject matter.")

§ 8[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?

Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014), confirms that the claim "as a whole" must be considered in the determination of patent-eligibility. *Alice* states that "[b]ecause the approach we made explicit in *Mayo* considers all claim elements, both individually and in combination, it is consistent with the general rule that patent claims 'must be considered as a whole.' *Diamond v. Diehr*, 450 U. S. 175, 188 (1981); see *Parker v. Flook*, 437 U. S. 584, 594

(1978) ('Our approach . . . is . . . not at all inconsistent with the view that a patent claim must be considered as a whole')." *Alice*, 134 S.Ct. at __ n.3.

§ 8[b][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 consider the judicial requirement to construe the subject matter under the "all elements" rule. There is a rich history of precedent from more than one hundred years ago by Justice Story that established the rule. *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. Ortmayer*, 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)).

The long line of case law concerning the "all elements" rule is denied in *Parker v. Flook*, 437 U.S. 584 (1978), an aberrational decision that was soon distinguished by the Court in *Diamond v. Diehr*, 450 U.S. 175 (1981). To the extent that *Flook* stands for the proposition that one may dissect a claim into its constituent elements to determine patent-eligibility based upon the patent-eligibility of one of the components, *Flook* was cabined by *Diamond v. Diehr*, 450 U.S. 175 (1981).

In *Diehr* the Court expressly stated that "[i]n determining the eligibility of [the patent applicants'] claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis." *Diehr*, 450 U.S. at 188.

§ 8[b][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. 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[.]" *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).

§ 8[c] Research "Preemption" as Basis to Deny Patent-Eligibility

§ 8[c][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." *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.).

§ 8[c][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. *Deuterium Corp. v. United States*, 19 Cl.Ct. 624 (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.)).

§ 8[c][3] The Preemption Argument in *Ariosa* is Mistaken

Mayo and *Alice* do not require a denial of patent-eligibility under the "preemption" theory which, as stated in *Alice*, provides 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*]

The public policy justification given above for exclusions from patent eligibility has focused on the need to keep the building blocks of science free to encourage future innovation. Thus, for example, in the *Myriad* case, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2116 (2013), the Supreme Court stated the "preemption" focus thusly:

> We have "long held that [35 USC § 101 defining patent-eligible subject matter] contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable." [ ] *Mayo*[*Collaborative Servs. v. Prometheus Labs., Inc*., 132 S. Ct. 1289, 1293 (2012)] (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'").

As quoted in *Myriad*, the public policy concern is thus of a "considerable danger that the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon them.'" The claims in the expected *Sequenom* appeal tie up nothing. Neither the fluid sample taken from the womb of the mother nor the DNA in that sample is claimed. Nothing is in the claimed invention that would in any even remote sense "inhibit future innovation."

But, in the *Sequenom* case, there is no claim to any DNA nor its use. The DNA that is the subject of the invention is merely to be *identified* as present or absent in this genetic testing invention. There is no discovery of a new property of any DNA: To the contrary, the DNA that is the object of the invention is merely to be identified as present or absent in the sample. Insofar as the DNA is part of the process – as part of a fluid sample where any DNA is amplified through polymerase chain reaction – the fluid sample holds no value whatsoever other than as a being a sample of the DNA from the fetus; this fluid sample is neither patented nor of any value other than as the object of the genetic test of the invention.

There is no preemption in *Ariosa* of the use of DNA in the future as that very DNA that is part of the bodily fluid sample in the testing method: The DNA is merely the subject of *identification* as the object of the claimed invention.

♦ ♦ ♦

§ 9. THE *SEQUENOM* PETITION FOR *CERTIORARI*

Sequenom v. Ariosa Diagnostics, the styling of the likely early 2016 petition for *certiorari* from *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __ (Fed. Cir. Dec. 2, 2015), *panel proceedings,* 788 F.3d 1371 (Fed. Cir. 2015), is now in line for an early 2016 petition for a writ of *certiorari.*

It is hardly surprising that the petitioner was unable to garner a majority of the Federal Circuit for rehearing *en banc*, given the track record of this appellate court in cases such as *CLS Bank Int'l v. Alice Corp.*, 717 F.3d 1269, 1277 (Fed. Cir., 2013)(en banc)(per curiam)(Lourie, J., joined by Dyk, Prost, Reyna, Wallach, JJ., concurring), *subsequent proceedings sub nom Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014), quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1293 (2012). *CLS Bank* represents a particularly illumining picture of a divided court with disparate views on various subjects. *See* § 9[c] *CLS Bank, a Case Study of Failed Federal Circuit Expertise.* It is perhaps useful in viewing the several opinions in the denial of rehearing *en banc* in *Ariosa* to view the various examples given in the cited analysis of the *CLS Bank* case.

§ 9[a] The Differing Views of Four Members of the Court

§ 9[a][1] The Lourie Concurrence (Joined by Moore, J.)

The second senior-most active member of the Court issued the following concurring opinion in the denial of rehearing en banc, joined by Moore, J.:

> The Supreme Court in *Mayo* determined that the claims in that patent "set forth laws of nature." It further held in *Mayo* that steps additional to those setting forth laws of nature in a claimed process must add something "that in terms of patent law's objectives ha[ve] significance" to the natural laws, such that those steps transform the process into an inventive application of those laws. *Mayo*, 132 S. Ct. at 1299. Moreover, the Court rejected "post-solution activity that is purely conventional or obvious" as not significant enough to bring a claimed invention within the realm of patent-eligible subject matter. *Id*. (internal quotation marks and alteration omitted).
>
> ***I find no principled basis to distinguish this case from *Mayo*, by which we are bound. I write separately to express some thoughts concerning laws of nature and abstract ideas, which seem to be at the heart of patent-eligibility issues in the medical sciences.
>
> Since the Supreme Court's decision in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), the issue of patent eligibility under § 101 has been of key importance in the adjudication of patent cases, particularly in the field of software. The Court's decisions in

Mayo[*Collaborative Servs. v. Prometheus Labs., Inc*., 132 S. Ct. 1289 (2012), 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), have further brought the focus onto the field of medical diagnostics.

The Supreme Court in *Mayo* determined that the claims in that patent "set forth laws of nature." It further held in *Mayo* that steps additional to those setting forth laws of nature in a claimed process must add something "that in terms of patent law's objectives ha[ve] significance" to the natural laws, such that those steps transform the process into an inventive application of those laws. *Mayo*, 132 S. Ct. at 1299. Moreover, the Court rejected "post-solution activity that is purely conventional or obvious" as not significant enough to bring a claimed invention within the realm of patent-eligible subject matter. *Id*. (internal quotation marks and alteration omitted).

Alice relates to the third specific exception to eligibility—abstract ideas—and its discussion also incorporates the requirement of an "inventive concept" beyond "conventional steps." It held that claims that amount to nothing more than *instruction to apply* an abstract idea are not patent eligible, although *application of the abstract idea may be*. In my view, neither of the traditional preclusions of laws of nature or of abstract ideas ought to prohibit patenting of the subject matter in this case.

Laws of nature are *exact* statements of physical relationships, deduced from scientific observations of natural phenomena. They are often represented by equations, and include such laws as the relationship between energy and mass ($E=mc^2$), the relationship between current and resistance (Ohm's Law), that between force, mass, and acceleration (F=ma), Maxwell's equations, Newton's laws of motion, and many more. Those laws, all agree, are not and should not be patent-eligible subject matter. But methods that utilize laws of nature do not set forth or claim laws of nature. All physical steps of human ingenuity utilize natural laws or involve natural phenomena. Thus, those steps cannot be patent-ineligible solely on that basis because, under that reasoning, nothing in the physical universe would be patent-eligible.

Abstract steps are, axiomatically, the opposite of tangible steps; that which is not tangible is abstract. But steps that involve machines, which are tangible, steps that involve transformation of tangible subject matter, or tangible implementations of ideas or abstractions should not be considered to be abstract ideas. In *Bilski*, the Supreme Court supported this proposition when it described our earlier machine-or-transformation test as a useful clue, albeit not the only test, for eligibility.

Conversely, abstract ideas are essentially mental steps; they are not tangible even if they are written down or programmed into a physical machine. *Alice,* in affirming this court, held that claims that amount to nothing significantly more than *instruction to apply* an abstract idea are not patent eligible. But the fact that steps are well-known, although relevant to other statutory sections of the patent law, does not necessarily make them abstract.

The claims at issue in Sequenom's patent are directed to methods for detecting paternally-inherited fetal DNA in maternal blood samples, and performing a prenatal diagnosis based on such DNA. Following *Mayo*, which held that certain steps merely recite natural laws and that the remaining steps must be sufficiently innovative apart from the natural laws, the panel in this case held that the claims do not involve patent-eligible subject matter. Appellants and amici have argued before us in briefs that a broad range of claims of this sort appear to be in serious jeopardy. It is said that the whole category of diagnostic claims is at risk. It is also said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern.

* * *

It is not disputed that fractionating blood, amplifying DNA, and analyzing DNA to detect specific gene sequences are known techniques in the art. As all other steps in the claims are individually well-known, the innovative aspect of the claims appears to be the improvement in the method of determining fetal genetic characteristics or diagnosing abnormalities of fetal DNA, consisting of *use of the non-cellular fraction of fetal DNA* obtained from a maternal blood sample.

* * *

[T]he claims here are directed to an actual use of the natural material of [cell-free fetal DNA] . They recite innovative and practical *uses* for it, particularly for diagnostic testing: blood typing, sex typing, and screening for genetic abnormalities. And it is undisputed that before this invention, the amplification and detection *of* [*cell-free fetal DNA*] *from maternal blood*, and use of these methods for prenatal diagnoses, were *not* routine and conventional. But applying *Mayo*, we are unfortunately obliged to divorce the additional steps from the asserted natural phenomenon to arrive at a conclusion that they add nothing innovative to the process.

* * *

As stated by Judge Lourie, "[t]he Supreme Court in *Mayo* determined that the claims in that patent 'set forth laws of nature.' It further held in *Mayo* that steps additional to those setting forth laws of nature in a claimed process must add something 'that in terms of patent law's objectives ha[ve] significance' to the natural laws, such that those steps transform the process into an inventive application of those laws. *Mayo*, 132 S. Ct. at 1299. Moreover, the Court rejected 'post-solution activity that is purely conventional or obvious' as not significant enough to bring a claimed invention within the realm of patent-eligible subject matter. *Id*. (internal quotation marks and alteration omitted)."

While the individual steps, *in vacuo,* may be obvious, the *combination* of those steps is nowhere suggested in the prior art.

* * *

It is not disputed that fractionating blood, amplifying DNA, and analyzing DNA to detect specific gene sequences are known techniques in the art. As all other steps in the claims are individually well-known, the innovative aspect of the claims appears to be the improvement in the method of determining fetal genetic characteristics or diagnosing abnormalities of fetal DNA, consisting of *use of the non-cellular fraction of fetal DNA* obtained from a maternal blood sample.

* * *

[T]he claims here are directed to an actual use of the natural material of [cell-free fetal DNA] . They recite innovative and practical *uses* for it, particularly for diagnostic testing: blood typing, sex typing, and screening for genetic abnormalities. And it is undisputed that before this invention, the amplification and detection *of* [*cell-free fetal DNA*] *from maternal blood*, and use of these methods for prenatal diagnoses, were *not* routine and conventional. But applying *Mayo*, we are unfortunately obliged to divorce the additional steps from the asserted natural phenomenon to arrive at a conclusion that they add nothing innovative to the process.

§ 9[a][2] The Dyk Concurrence with Denial of Rehearing En Banc

I concur in the court's denial of rehearing en banc. In my view the framework of *Mayo* and *Alice* is an essential ingredient of a healthy patent system, allowing the invalidation of improperly issued and highly anticompetitive patents without the need for protracted and expensive litigation. Yet I share the concerns of some of my colleagues that a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in *Mayo*) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena. This leads me to think that some further illumination as to the scope of *Mayo* would be beneficial in one limited aspect. At the same time I think that we are bound by the language of *Mayo*, and any further guidance must come from the Supreme Court, not this court.

* * *

The language of *Mayo* is clear. The *Mayo* Court found that prior Supreme Court decisions "insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012) (quoting *Parker v. Flook*, 437 U.S. 584, 594 (1978)). Patent claims directed to laws of nature are ineligible under 35 U.S.C. § 101 when, "(*apart* from the natural laws themselves) [they] involve well-understood, routine, conventional activity previously engaged in by researchers in the field." *Id.* (emphasis

added). Reviewing the Court's earlier *Flook* decision, the *Mayo* Court determined that Flook's claim to a chemical process applying an "apparently novel mathematical algorithm," *id.* at 1298, was ineligible under § 101 because the steps of the process "were all 'well known,' to the point where, *putting the formula to the side*, there was no 'inventive concept' in the claimed application of the formula," *id.* at 1299 (quoting *Flook*, 437 U.S. at 594) (emphasis added). "[S]imply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." *Id.* at 1300. In other words, *Mayo* states that the inventive concept necessary for eligibility must come in the application analyzed at step two, rather than from the discovery of the law of nature itself.

Alice subsequently confirmed that the two-step framework articulated in *Mayo* is a unitary rule that applies equally "for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014) (citing *Mayo*). *Alice* explained,

"First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, what else is there in the claims before us? . . . *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."

Id. (emphasis added) (alterations, citations, and quotation marks omitted). "*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." *Id.* at 2357 (emphasis added) (quotation marks omitted). Thus *Alice* also holds that inventive concept must be found at step two of the framework.

Mayo has unambiguously announced a generally applicable test for determining subject-matter eligibility under § 101 with respect to laws of nature, and we are bound to follow it. We cannot confine *Mayo* to its facts or otherwise cabin a clear statement from the Supreme Court. "[O]nce the Court has spoken, it is the duty of other courts to respect that understanding of the governing rule of law." *Rivers v. Roadway Express, Inc.*, 511 U.S. 298, 312 (1994). A court of appeals must not "confus[e] the factual contours of [a Supreme Court decision]for its unmistakable holding" to arrive at a "novel interpretation" of that decision. *Thurston Motor Lines, Inc. v. Jordan K. Rand, Ltd.*, 460 U.S. 533, 534–35 (1983) (per curiam). As we have recognized, "[a]s a subordinate federal court, we may not so easily dismiss [the Supreme Court's] statements as dicta but are bound to follow them." *Ariad Pharm., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1347 (Fed. Cir. 2010) (en banc) (citing *Stone Container Corp. v. United States*, 229 F.3d 1345, 1349–50 (Fed. Cir. 2000)).

* * *

The panel thus held correctly that *Mayo* is controlling precedent that governs the outcome here. The panel's opinion aptly states and applies the two-step frameworkof *Mayo*. "First, we determine whether the claims at issue are directed to a patent-ineligible concept." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015) (citing *Mayo*, 566 U.S. at 1292). "[T]he claims at issue, as informed by the specification, are generally directed to detecting the presence of a naturally occurring thing or a natural phenomenon, [cell-free fetal DNA] in maternal plasma or serum. . . . [T]he claimed method begins and ends with a naturally occurring phenomenon." *Id.* at 1376. At the second step of the *Mayo* framework, the panel determined that "[t]he method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect [cell-free fetal DNA] ." *Id.* at 1377. The panel therefore found that the claims were not patent eligible under § 101. *Id.* at 1378.

* * *

The *Mayo*/*Alice* framework works well when the abstract idea or law of nature in question is well known and longstanding, as was the situation in *Mayo* itself (as discussed below), earlier Supreme Court cases, and in many of our own recent cases where we have found claims patent ineligible under § 101. Where the abstract idea or law of nature is well known and longstanding, there is no basis for attributing novelty to that aspect of the claimed invention.

Also, it seems to me that the *Mayo*/*Alice* framework works well with respect to abstract ideas. In my view, claims to business methods and other processes that merely organize human activity should not be patent eligible under any circumstances. *See Alice*, 134 S. Ct. at 2360 (Sotomayor, J., concurring); *In re Bilski*, 545 F.3d 943, 972 (Fed. Cir. 2008) (en banc) (Dyk, J., concurring). In any event, departing from the *Mayo*/*Alice* framework with respect to abstract ideas (as opposed to discoveries of natural laws and phenomena) would create serious risks of undue preemption because of the difficulty in distinguishing between new and established abstract ideas.
But, as I see it, there is a problem with *Mayo* insofar as it concludes that inventive concept cannot come from discovering something new in nature—*e.g.*, identification of a previously unknown natural relationship or property. In my view, *Mayo* did not fully take into account the fact that an inventive concept can come not just from creative, unconventional application of a natural law, but also fromthe creativity and novelty of the discovery of the law itself. This is especially true in the life sciences, where development of useful new diagnostic and therapeutic methods is driven by investigation of complex biological systems. I worry that method claims that apply newly discovered natural laws and phenomena in somewhat conventional ways are screened out by the *Mayo* test. In this regard I think that *Mayo* may not be entirely consistent with the Supreme Court's decision in *Myriad*.

In *Myriad* the patent applicant discovered a previously unknown natural phenomenon: the sequences of the BRCA1 and BRCA2 genes and their connection with cancer. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2112–13 (2013). While the Court found ineligible Myriad's claims to naturally occurring DNA sequences, it suggested that "new *applications* of knowledge about the BRCA1 and BRCA2 genes" could generally be eligible, with reference to claim 21 of U.S.Patent No. 5,753,441 (discussed further below).[4] *Id.* at 2120. *Myriad* thus appeared to recognize that an inventive concept can sometimes come from discovery of an unknown natural phenomenon, not just from unconventional application of a phenomenon. As *Myriad* emphasized, the first party with knowledge of a law of nature, natural phenomenon, or abstract idea should be "in an excellent position to claim applications of that knowledge." *Id.* (quoting *Ass'n. for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1349 (Fed. Cir. 2012) (Bryson, J.,concurring in part and dissenting in part)).

The primary concern with a patent on a law of nature is undue preemption—the fear that others' innovative future applications of the law will be foreclosed. *See O'Reilly v. Morse*, 56 U.S. 62, 113 (1853); *Mayo*, 132 S. Ct. at 1301. As *Mayo* emphasized, "there is a danger that the grant of patents that tie up the[ ] use [of laws of nature] will inhibit future innovation premised upon them . . . ." 132 S. Ct. at 1301; *see also id.* at 1304 (highlighting "the kind of risk that underlies the law of nature exception, namely the risk that a patent on the law would significantly impede future innovation"). * * * [footnotes deleted]

§ 9[a][3] The Newman Dissent from denial of rehearing En Banc

The opinion by Judge Newman, dissenting from denial of the petition for rehearing en banc, nails the reason why the instant case need *not* be governed by the earlier Supreme Court precedent: She explains that "[in the *Myriad* case], *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013),] the Court stat[ed] that 'this case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes.' 133 S. Ct. at 2120 (emphasis original). The Court further explained its holding, stating that: '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.' *Id.*"

§ 9[b] Unnecessarily and Incorrectly Following *Dicta* from *Mayo* and *Alice*

The court reads sweeping *dicta* in Supreme Court cases such as *Mayo* as binding precedent, and not for what it is, *obiter dicta.* In his concurrence, joined by Judge Moore, Judge Lourie states that he "find[s] no principled basis to distinguish this case from *Mayo*, by which we are bound." He furthermore states

that the Supreme Court "held in *Mayo* that steps additional to those setting forth laws of nature in a claimed process must add something 'that in terms of patent law's objectives ha[ve] significance' to the natural laws, such that those steps transform the process into an inventive application of those laws. *Mayo*, 132 S. Ct. at 1299. Moreover, the Court rejected 'post-solution activity that is purely conventional or obvious' as not significant enough to bring a claimed invention within the realm of patent-eligible subject matter." (citations omitted)

While it is admirable that the court follow the teachings of the Supreme Court, Supreme Court opinions are not to be read in a vacuum, but should be considered as part of the fabric of overall Supreme Court case law: *Dicta* in recent cases should not be so broadly read as to directly conflict with *holdings* in other Supreme Court case law.

As just one example, the court fails to consider the invention *as a whole* in its determination of patent-eligibility. But, to dissect claims to their elements and view claims on an element by element basis is to disregard the "all elements" rule of the nineteenth century that continues to the present day. *See* § 9[b][3], *"Inventive" Subject Matter under the "All Elements" Rule.*

§ 9[c] "Inventive" Subject Matter under the "All Elements" Rule

Reading the body of Supreme Court case law as a whole, one sees a broader picture of when subject matter is "inventive": "Such secondary considerations as *** long felt but unsolved needs * * * might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 506 (2007)(quoting *Graham* v. *John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966))

As explained in the *Adams Battery* case, "[w]hile 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)." The *Adams Battery* case, *United States v. Adams*, 383 U.S. 39, 48-49 (1966).

The invention in the *Ariosa* case clearly meets the demanding standards for "inventive" subject matter even under the extreme *Sakraida* case: "It has long been clear that the Constitution requires that there be some "invention" to be

entitled to patent protection. *Dann v. Johnston*, 425 U.S. 219 (1976). As we explained in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248, 267 (1851): "[U]nless more ingenuity and skill . . . were required . . . than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that decree of skill and ingenuity which constitute essential elements of every invention." *Sakraida v. Ag Pro, Inc*, 425 U.S. 273, 279 (1976).

In *Ariosa*, there is absolutely no suggestion in the prior art to not only *combine* known elements but also to *modify* the fluid sample containing the DNA to create a larger amount of DNA. "When determining the patentability of a claimed invention which combines two known elements, `the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.'" *Akamai Tech. v. Cable & Wireless Internet Services*, 344 F.3d 1186, 1196 (Fed. Cir., 2003)(quoting *In re Beattie*, 974 F.2d 1309. 1311-12 (Fed.Cir.1992) (quoting *Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1462 (Fed.Cir.1984)).

It is furthermore not the properties of the DNA that are at the essence of the invention but, rather, the *existence* of that DNA in a bodily fluid sample not recognized to contain that DNA.

Whether an invention is nonobvious under 35 USC § 103 – or "inventive" under the case law that evolved prior to the 1952 codification resulting in this statutory requirement – is dependent upon the claimed invention *as a whole*, as discussed more fully at § 8[b][1], *Flook versus the "All Elements" Rule.*

While there *is* support in *Parker v. Flook*, 437 U.S. 584 (1978), for dissecting a claim into its elements in determining patent-eligibility, this approach is completely at odds with the "all elements" rule that developed in the nineteenth century. *See* § 8[b][1], *Flook versus the "All Elements" Rule* (citing *Barrett v. Hall*, 2 F.Cas. 914, 924 (No. 1047)(D. Mass. 1818)(Story, J., riding circuit); *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.); *Eames v. Godfrey*, 68 U.S. (1 Wall.) 78, 79 (1864); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 335-37 (1879); *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. Ortmayer*, 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)).

In any event, *Parker v. Flook* was cabined just three years after that decision by *Diamond v. Diehr*, 450 U.S. 175 (1981). To the extent that *Flook* stands for the proposition that one may dissect a claim into its constituent elements to determine patent-eligibility based upon the patent-eligibility of one of the components, *Flook* was cabined by *Diamond v. Diehr*, 450 U.S. 175 (1981).

In *Diehr* the Court expressly stated that "[i]n determining the eligibility of [the patent applicants'] claimed process for patent protection under § 101, their *claims must be considered as a whole*. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis." *Diehr*, 450 U.S. at 188.

§ 9[d] The "Inventive" Feature of the Claimed Combination

When the claimed invention *including all elements* is viewed, it is manifest that the *claimed* subject matter *is* "inventive", as detailed at § 8[b][2], *The "Inventive" Feature of the Claimed Combination.* As noted in that section, "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[.]" *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 as explained in detail in § 8[b][2], *The "Inventive" Feature of the Claimed Combination.*

§ 9[e] There is No Preemption of a Natural Phenomenon

As noted in the concurrence by Judge Dyk, more fully quoted at § 9[a][2], *The Dyk Concurrence with Denial of Rehearing En Banc*, "[t]he primary concern with a patent on a law of nature is undue preemption—the fear that others' innovative future applications of the law will be foreclosed. *See O'Reilly v. Morse*, 56 U.S. 62, 113 (1853); *Mayo*, 132 S. Ct. at 1301. As *Mayo* emphasized, 'there is a danger that the grant of patents that tie up the[ ] use [of laws of nature] will inhibit future innovation premised upon them . . . .' 132 S. Ct. at 1301; *see also id.* at 1304 (highlighting 'the kind of risk that underlies the law of nature exception, namely the risk that a patent on the law would significantly impede future innovation')."

Even following the preemption argument said to be based on *O'Reilly v. Morse*, cf. Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. 565, 594-96 (2015), there is clearly no "preemption" of any law of nature in *Ariosa* because the claims are *combination* claims which, under the "all elements" rule, are never infringed by the mere practice of one of the elements.

There simply is no preemption of a natural phenomenon in the *Ariosa* case. The preemption question is dealt with in great detail at § 8[c][2], *The Fundamental Issue of "Research Preemption",* which points a finger at the Federal Circuit for its failure to disown aberrant precedent that suggests that there is no right to experiment "on" a patented invention. The aberrant precedent may be traced to the *Deuterium* line of case law. *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.)).

There is no preemption under any standard in *Ariosa.* As pointed at out at § 8[c][3], *The Preemption Argument in Ariosa is Mistaken*:

> 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.

§ 9[f] The Mossoff-Noonan "23 Professors" Amicus Brief

An important contribution was made to the understanding of the patent-eligibility issues in an *amicus* brief by a group of academics, styled, here, as the "Mossoff-Noonan '23 Professors' Amicus Brief":*

> The panel decision exceeded the scope of the Supreme Court's § 101 jurisprudence in distinguishing patents claiming laws of nature, natural phenomena, and abstract ideas from patents claiming patent-eligible applications of those concepts. *** [D]evelopment and commercialization of prenatal genetic diagnostic tests [as in this case] is exactly the type of twenty-first-century innovation the patent system is designed to promote as a historically "unforeseen invention." *Bilski v. Kappos*, 561 U.S. 591, 605 (2010). [T]he panel's analysis is not even "a sufficient basis for evaluating processes similar to those in the Industrial Revolution," because if applied consistently it would call into question nineteenth-century patented innovation the Supreme Court deemed valid. *Id.* at 605.

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*This is an excerpt from the *Brief of Twenty-Three Law Professors in Support of Appellant's Petition for Rehearing En Banc* in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.,* 788 F.3d 1371 (Fed. Cir. 2015). The brief was principally coauthored by Prof. Adam Mossoff (George Mason University) and Dr. Kevin E. Noonan (McDonnell Boehnen Hulbert & Berghoff LLP), also on behalf of Prof. Dan L. Burk (California Irvine); Prof. Bernard Chao (U. Denver); Prof. Ralph D. Clifford (U. Massachusetts); Prof. Christopher A. Cotropia (U. Richmond); Prof. Gregory Dolin (U. Baltimore); Prof. Richard A. Epstein (NYU); Prof. Christopher Frerking (U. New Hampshire); Prof. Yaniv Heled (Georgia State); Prof. Timothy Holbrook (Emory University); Prof. Christopher M. Holman (UMKC); Prof. Gus Hurwitz (Nebraska); Prof. Mark D. Janis (Indiana); Prof. Sean M. O'Connor (U. Washington); Prof. Kristen Osenga (U. Richmond); Prof. Lee Petherbridge (Loyola Law School); Prof. Michael Risch (Villanova); Prof. Mark F. Schultz (Southern Illinois); Prof. Sean B. Seymore (Vanderbilt); Prof. Ted Sichelman (U. San Diego); Prof. Brenda M. Simon (Thomas Jefferson); Prof. Shine Tu (West Virginia); and Prof. Saurabh Vishnubhakat (Texas A&M).

I The Panel Decision Undermines Twenty-First-Century Innovation That The Patent System Is Designed To Promote And Protect

The panel's decision contravenes the *Bilski* Court's injunction that § 101 tests should not impede the progress of future innovation. The massive research and development into new technological applications of genetic diagnostic testing methods exemplifies the "progress of . . . useful Arts" the patent system is intended to promote and secure to its creators. [U.S. Const. art. 1, § 8, cl. 8.]

As the close relationship between genetic variation (and mutational injury) and disease has become more clear as a result of massive research and development (R&D) expenditures, the value of genetic diagnostic tools has increased exponentially. Experts now estimate that 60-70% of all medical treatment decisions are based on the results of diagnostic tests.[The Importance Of Diagnostics, http://www.biomerieux.com/en/importance-diagnostics (last visited Aug. 18, 2015).] Such tests have immense benefits for patient care and greatly reduce associated costs (including decreasing hospitalization and avoiding unnecessary treatment). [Roche, Annual Report 2014, 33 (2015), available at http://www.roche.com/gb14e.pdf.]

The economics of innovative diagnostic tests reflect exactly the economic justification for the patent system: the cost of applying a genetic diagnostic test is relatively low, but the ex ante R&D cost is enormous and is not reflected in the marginal cost of the medical test itself. According to one study, the average cost to develop and commercialize a diagnostic testing technology in the United States is between $50-75 million and can exceed $100 million for developing and commercializing novel diagnostic technologies. [*Mystery Solved! What is the cost to develop and launch a Diagnostic?*, Diaceutics Group, http://www.diaceutics.com/mystery-solved-what-cost-develop-and-launch-diagnostic (last visited Aug. 18, 2015).] Screening for diseases with complex genetic interactions, like diabetes, heart disease, and cancer, require even greater investments. As the *Bilski* Court recognized, the patent system exists to promote new inventions on the frontier of human technological knowledge like genetic testing methods, which by necessity require massive R&D expenditures that can only be recouped via the protections offered by property rights in this innovation.

The panel decision contravenes this insight by the Supreme Court because it threatens to preclude many genetic and other diagnostic tests from the ambit of patent protection. It disincentivizes making the massive R&D investments required to create this new innovation in the twenty-first century. This is neither hyperbole nor conjecture. For example, Accelerate Diagnostics recently warned its investors that it "incurred significant costs in connection with the development and commercialization of [its] [diagnostic testing] technology" and "[i]f we are unable to effectively protect our . . . intellectual property, our business would be harmed." [Accelerate Diagnostics, *2014 Annual Report*, 23 (2015), available at http://ir.axdx.com/secfiling.cfm?filingID=1000096-15-20&CIK=727207.]

II. The Panel's Analysis Contradicts § 101 Jurisprudence As Evidenced By How It Cast Doubts on Validity of Classic Method Patents

In *Mayo Collaborative Services v. Prometheus Laboratories*, the Supreme Court recognized that "too broad an interpretation of this exclusionary principle [regarding laws of nature, natural phenomena and abstract ideas] could eviscerate patent law. For

all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." [*Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1293 (2012).] Reflecting similar concerns, the *Bilski* Court rejected a § 101 test developed for assessing nineteenth-century process patents because it failed in properly "determining the patentability of inventions in the Information Age" today. [*Bilski*, 561 U.S. at 605. The Court further warned that "[a] categorical rule denying patent protection for 'inventions in areas not contemplated by Congress . . . would frustrate the purposes of the patent law." *Id.* (citing *Diamond v. Chakrabarty*, 447, U.S. 303, 315 (1980)).]

These admonitions by the Supreme Court directly apply to this case, because not only does the panel decision threaten an entire field of twenty-first-century inventive activity, it would also cast serious doubt about classic nineteenth-century patented innovation either validly issued under the patent laws or sustained by the Supreme Court. There are too many historical patents and Supreme Court decisions to discuss them all within the constraints of this brief, [*see* Michael Risch, *Nothing is Patentable*, FLORIDA L. REV. F. (2015), available at http://ssrn.com/abstract=2642361 (noting classic patents called into doubt).

[U.S. Patent No. X00001 (issued July 31, 1790),] and thus we will identify only a few exemplars, including the first patent issued in 1790 on a method for making potash.[U.S. Patent No. X00001 (issued July 31, 1790).]

Many judges and scholars cite to *O'Reilly v. Morse*, 56 U.S. 62 (1853), because the Supreme Court famously invalidated Claim 8 of Morse's patent, but many today may not remember that the *Morse* Court explicitly affirmed the validity of the first seven claims in Morse's patent. [*See Morse*, 56 U.S. at 112 ("We perceive no well-founded objection . . . to his right to a patent for the first seven inventions set forth in the specification of his claims.").] This is important, because Claim 1 recited a method of operating an electro-magnetic telegraph that could be invalid under the panel's application of *Mayo*. Claim 1 is not quoted in Chief Justice Roger Taney's opinion in *Morse*, and so to understand this point, it is necessary to quote the relevant language from the claim:

> First. . . . what I specially claim as my invention and improvement, is making use of the motive power of magnetism, when developed by the action of such current or currents substantially as set forth in the foregoing description of the first principal part of my invention, as means of operating or giving motion to machinery which may be used to imprint signals upon paper or other suitable material, or to produce sounds in any desired manner, for the purpose of telegraphic communication at any distances.
>
> [U.S. Reissue Patent No. 117 (issued June 13, 1848).]

Under the panel's interpretation of step one of the *Mayo* test, this claim begins with patent ineligible natural phenomenon ("the motive power of magnetism") and ends with an abstract idea ("communication at any distances").

According to the panel, the second step in the *Mayo* test then requires assessing whether the claim also recites merely "well-understood, routine, and conventional activity," [*Ariosa,* 788 F.3d at 1377,] and each remaining element in Morse's Claim 1 recites conventional activity for the art in his time. First, Morse acknowledges in his specification that "it had been essayed to use the currents of electricity or galvanism for telegraphic purposes" before his invention, and he even acknowledges later in Claim 1 that "[t]here are various known methods of producing motion by electro-magnetism." [U.S. Reissue Patent No. 117 (issued June 13, 1848).] Second, the steps he states in Claim 1 of "operating or giving motion to machinery," "imprinting signals upon paper or other suitable material," and "produc[ing] sounds," when assessed individually were undeniably routine and conventional in the 1830s when Morse invented his electro-magnetic telegraph. [For an historical analysis of the invention, patenting, commercialization and litigation of Morse's electro-magnetic telegraph, *see* Adam Mossoff, *O'Reilly v. Morse* (Aug. 18, 2014), available at http://ssrn.com/abstract=2448363.
[1] U.S. Patent No. 174,465 (issued Mar. 7, 1876).] Accordingly, the *Ariosa* panel's application of the *Mayo* test, if applied to Claim 1 of Morse's patent in the same way the panel applied it to Sequenom's patent, leads to the conclusion that Morse's Claim 1 is arguably unpatentable subject matter. But this directly contradicts the Supreme Court's analysis and decision in *Morse* that Claim 1 is valid.

Another prominent and more commonly cited example of a patentable invention is Claim 5 of Alexander Graham Bell's patent on the telephone, [U.S. Patent No. 174,465 (issued Mar. 7, 1876),] which was affirmed by the Supreme Court in *Dolbear v. American Bell Telephone Company*, 126 U.S. 1 (1888). Claim 5 recites:

> The method of and apparatus for transmitting vocal or other sounds telegraphically . . . by causing electrical undulations, similar in form to the vibrations of the air accompanying the said vocal or other sounds.

Again, applying the *Ariosa* panel's analysis to Claim 5 in Bell's patent leads to the same conclusion reached for Claim 1 of Morse's patent. First, under *Mayo* step one, Claim 5 begins and ends with "vocal and other sounds," and concerns generally the mere transmission of those sounds by electrical undulations. These concepts are natural phenomena, and thus are patent ineligible *per se*. The claim also does not recite anything significantly more than the ineligible concepts themselves that was not routine, well-understood and conventional, because telegraphic transmission and electrical undulation had been long known in the art. [*See* CHRISTOPHER BEAUCHAMP, INVENTED BY LAW: ALEXANDER GRAHAM BELL AND THE PATENT THAT CHANGED AMERICA 58-85 (2014) (recounting claims of many prior and existing uses of electrical currents in telegraphic communication).] Again, contrary to the Supreme Court's own analysis and decision in

1888, the *Ariosa* panel's analysis leads to the logical conclusion that Bell's famous Claim 5 is unpatentable subject matter.

Perhaps most surprising is that the first U.S. patent ever granted would be invalid under the panel's application of the *Mayo* two-step test. The first patent issued in 1790 to Samuel Hopkins for his method of making potash. [U.S. Patent No. X00001 (granted July 31, 1790).] This method involved well-known steps such as burning and dissolving ash, and Hopkins' "inventive" contribution was in the timing and specific order of the steps. [*See* Henry M. Payntor, *The First Patent* (rev., 1998), available at http://www.me.utexas.edu/~longoria/paynter/hmp/The_First_Patent.html.] Both of these aspects of Hopkins' patent considered individually would be deemed basic facts or concepts of conventional human activity, and under the *Ariosa* panel's application of the *Mayo* test are arguably unpatentable subject matter.

This is significant because Hopkins' patent was signed by Thomas Jefferson as Secretary of State and as a member of the committee created under the 1790 Patent Act who reviewed Hopkins' application. Jefferson was both a drafter of some of the early patent laws and has long been known for his views that patents should be severely restricted in their issuance to inventors. [*See* Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent "Privilege" in Historical Context*, 92 CORNELL L. REV. 93, 959-63 (2007); *see also* Justin Hughes, *Copyright and Incomplete Historiographies: Of Piracy, Propertization, and Thomas Jefferson*, 79 S. CAL. L. REV. 993, 1026-34 (2006) (discussing Jefferson's contradictory views on the legitimacy of patents and copyrights).] Moreover, Hopkins' patent was issued under the 1790 Patent Act, which was drafted by many of the original Framers of the Constitution who were then serving in Congress. Justices and constitutional scholars recognize legislation from the First Congress as having significant import as to the meaning of the Constitution. [*See, e.g., Wisconsin v. Pelican Ins. Co.*, 127 U.S. 265, 297 (1888) (quoting 1789 Judiciary Act as primary evidence of meaning of Article III, § 2); Neal Katyal & Paul Clement, *On the Meaning of "Natural Born Citizen,"* 128 HARV. L. REV. F. 161, 161 (2015) ("The Supreme Court has long recognized that two particularly useful sources in understanding constitutional terms are British common law and enactments of the First Congress.").] This includes the Copyright and Patent Clause's authorization for Congress to secure an "exclusive Right" to "Inventors" for their "Discoveries" in order to advance the "progress of . . . useful Arts." Thus, when a contemporary court reaches a decision that calls into question a patent validly issued under the 1790 Patent Act and signed by Jefferson himself, it is cause to question whether this court has applied the law correctly.

As has been made clear, the panel decision not only contradicts the *Bilski* Court's injunction that § 101 is a "dynamic provision designed to encompass new and unforeseen inventions," *Bilski,* 561 U.S. at 605, such as the revolutionary genetic diagnostic testing methods made possible by the modern biotech revolution, it also casts doubt on classic patented innovation validly issued or upheld by the Supreme Court. This suggests that the *Ariosa* panel has misapplied § 101 jurisprudence and that the error is significant enough to warrant *en banc* consideration.

♦ ♦ ♦

§10. PTO PATENT-ELIGIBILITY EXAMINATION GUIDANCE

§ 10[a] A Five Step Proposal for Patent Eligibility Examination

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 the following strict rules for examination:

Step One: Without considering judicial exceptions to patent-eligibility, is the claimed subject matter any of a "new and useful process, *** manufacture, or composition of matter[.]"? If the answer is "yes", go to Step Two.

Step Two: If the answer to Step One is affirmative, is there any implication of a "law of nature," "natural phenomenon," or "abstract idea" in any element of the claim? If the answer is "no", there is no issue of patent-eligibility. If the answer is "yes", go to Step Three.

Step Three: Determine the literal scope of the metes and bounds of the claim in question which define the scope of the invention.

To determine patent-eligibility it is improper to dissect the claimed invention into its elements. Thus, "[i]n determining the eligibility of [the patent applicants'] claimed process for patent protection under § 101, their *claims must be considered as a whole*. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis." *Diamond v. Diehr*, 450 U.S. 175, 188 (1981)(emphasis added). *Parker v. Flook*, 437 U.S. 584 (1978), is no longer viable to the extent that it is inconsistent with this subsequent statement in *Diehr*.

Diehr is a restatement of the "all elements" rule supported by numerous Supreme Court cases. *See* § 8[b][1], *Flook versus the "All Elements" Rule.*

Step Four: Is the claimed subject matter *as a whole* "inventive" within the meaning of the statutory test of nonobviousness under 35 USC § 103 (superseding the *Hotchkiss* case law standard).

Whether or not one – or all – of the individual elements of the claimed invention is nonobvious is not necessarily dispositive as to whether the claimed invention is "inventive". The claimed invention *as a whole* may very well be 'inventive". Thus, "[m]ost inventions arise from a combination of old elements and each element may often be found in the prior art." *In re Kahn*, 441 F.3d 977, 984 (Fed. Cir. 2006)(Linn, J.)(citing *In re Rouffet*, 149 F.3d 1350, 1357 (Fed.Cir. 1998)). Even though each element may, standing alone, be obvious is not the end of the inquiry: "[M]ere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole." *Id.* (citing *Roufett,* 149 F.ed at 1355, 1357).

Step Five: If the answer to Step Four is *affirmative*, then the claimed subject matter meets the patent-eligibility standard of 35 USC §101.

§ 10[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".

Only Section 103 provides a clear statutory definition of the prior art, updated for the modern world of first-to-file in the *Leahy Smith America Invents Act* of 2011 that defines a nonobvious contribution to the art in terms of a prior art standard where "the claimed invention was * * * available to the public before the effective filing date of the claimed invention[.]" 35 USC § 102(a)(1).

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.

.

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).

§ 10[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.

§ 10[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.

§ 10[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.

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* § 710, *"Inventive", Nonobvious Subject Matter without Question.*

§ 10[f] An Uneven Approach from the Patent Bar

An applicant should have the right to claims to an invention that include an "abstract" (or other patent-ineligible) element as part of a *combination* claim where (a) the claim as properly interpreted is not limited to that "abstract" concept because it is only one element of the claimed combination; and (b) after a full consideration of the state of the prior art, the properly interpreted combination claim is to an "inventive" or "nonobvious" combination – whether or not an individual element, standing alone, is "inventive" or "nonobvious".

Yet, seemingly sophisticated groups of patent practitioners have taken comfort in fact-based Patent Office guidance. The largest bar organization in the United States offered its comments that seemingly ignore this fundamental

approach to patent-eligibility: "The [ABA] Section applauds the Office's work [in its *July 15, 2015 Update: Subject Matter Eligibility*, 80 Federal Register 45429 (July 30, 2015),] to provide twenty-seven examples that analyze practical examples of claims under the two-part Mayo test for subject-matter eligibility. These examples help both examiners and stakeholders to reach a common understanding and advance prosecution." Letter from Theodore H. Davis, Jr., Chair, American Bar Association Section of Intellectual Property Law to the Hon. Michelle K. Lee, Under Secretary of Commerce (October 28, 2105) responsive to the *July 15, 2015 Update: Subject Matter Eligibility*, 80 Federal Register 45429 (July 30, 2015).

Comparing factual scenarios among the various case law precedents is a dangerous exercise particularly where the *primary* determinations of the scope of the claim under consideration and whether the claim to "inventive" subject matter are not the focus of an inquiry. For example, in the nine (9) page, single spaced Davis letter there is no consideration of the two part analysis of claim scope and "inventive" subject matter. (One could consider, *arguendo*, that a claim need not be to "inventive" subject matter and still be patent-eligible under Section 101. But, if the claimed invention is not "inventive" or "nonobvious", then the claimed subject matter, even though patent-*eligible* would not be patentable. So, this is a distinction without practical consequence.)

How does the Examiner determine whether there is or is not an "inventive" or "nonobvious" claimed combination without a search of the prior art? Nowhere is there any mention by the American Bar Association of the need to *search* the claimed invention to make a determination of whether the claimed subject matter is "inventive":

§ 11. Lefstin, Starting Over with *Mayo* and *Alice*

Professor Lefstin takes the seemingly radical (but probably correct) view that, in essence, says that we need to play a mulligan in terms of abandoning a long garbled case law field, and start over again keyed to the recent cases of *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), and *Alice Corporation Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014).

He first sets the table, pointing to the impossibility of reconciling the various cases of the past forty years:

> The major obstacle to consistency and predictability in the field is the incoherence of the Supreme Court's opinions. Over the last forty years, the Supreme Court's subject-matter jurisprudence has shifted radically in both rationale and analysis not only from the doctrine's historical moorings, but also within the Court's modern cases themselves. *** [O]ver the last four decades, the Court has pretended that its subject-matter jurisprudence is a coherent whole. The result is that lower tribunals can select from a patchwork collection of incongruous analyses and rationales in order to yield a desired outcome.

Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence Of Abstractions*, 16 N. C. J. L. & Tech. 647, 650 (2015)(footnotes omitted).
Professor Lefstin's solution is to focus upon *Mayo* and *Alice*:

> [The point is not] to criticize the Court's jurisprudence, nor to attempt a reconciliation of that jurisprudence into a coherent whole, nor to propose a grand unified theory of patent-eligible subject matter. Rather, this Article takes the Court's decisions in *Mayo* and *Alice* as a given. Its central thesis is that the test of patent eligibility pronounced in *Mayo* and *Alice* represents an opportunity to discard much of the doctrinal detritus that has accumulated around the law of patent-eligible subject matter over the last forty years. By focusing on the structure of the *Mayo*/*Alice* test, as well as the rationale for subject matter exclusions articulated in *Mayo* and *Alice*, this Article derives meanings for the key notions of "inventive concept" and "abstract idea" that the Court has left undefined. Under these meanings, two significant categories of inventions are shown to be patent-eligible subject matter under *Mayo* and *Alice*: specific applications of newly discovered laws of nature and specific, human-created information-processing methods that are implemented on computers.

Lefstin, 16 N. C. J. L. & Tech. at 650-51.

Continuing, Professor Lefstin states that:

> [I]t is time to admit that the Supreme Court's opinions cannot be reconciled. Rather, the solution is to recognize the significance of the Court's reaffirmation of *Mayo* in *Alice*. For *Mayo* made three things clear. First, *Mayo* grounded subject-matter exclusions on a utilitarian rationale: fundamental principles—laws of nature, natural phenomena, and abstract ideas—are excluded because they are the "building blocks" of future advances; monopolization of these principles by patents might tend to impede innovation more than promote it. Second, *Mayo* defined the § 101 inquiry as a distinction between ineligible claims to fundamental principles themselves and claims to patent-eligible applications of those principles. Third, *Mayo* held that an "inventive concept" is necessary to transform a fundamental principle into a patent-eligible application. And while the Court's subsequent opinion in *Myriad* made no reference to the "inventive concept" analytical framework, *Alice* affirmed that the two-stage inquiry suggested by *Mayo* is the framework for patent-eligibility under § 101: first, determine whether a claim is directed to a fundamental principle; second, if a claim is directed to an ineligible principle, ask whether the claim contains an "inventive concept" sufficient to transform the underlying principle into a patent-eligible application.

Lefstin, 16 N. C. J. L. & Tech. at 657-58 (2015)(footnotes omitted)

§ 12. CONCLUSION

Will the Supreme Court grant *certiorari* in the *Sequenom* case?

Patent system proponents may at first blush jump to the conclusion that grant of *certiorari* would be good for the patent system. But, if *certiorari* is denied, this may be the better outcome, to give the Federal Circuit a chance to clean up the current situation of uncertainties in the patent law.

The Federal Circuit has abdicated its responsibility to provide a coherent patent law in this area. This is exemplified through its flagrant disregard of precedent as to the Story line of case law establishing the right of the public to experiment *on* a patented invention. The Federal Circuit has also failed to pay more than superficial attention to much of the body Supreme Court case law as exemplified by its rote acceptance of the preposterous view that patent-eligibility case law dates back more than 150 years to cited English and American precedent that has nothing to do with patent-eligibility.

After *Alice*, and assuming denial of *certiorari* in *Sequenom*, there are several points that the Federal Circuit must address if patent-eligibility case law is to be refashioned in a way consistent with precedent and which will keep the door open to patenting new innovations.

First of all, the Supreme Court is *correct* that there should be no preemption of the laws of nature, natural phenomena, and abstract ideas because the fundamental point of the Constitutional power to grant patents is to "Promote the Progress of *** the Useful Arts." Early in the history of this nation the leading scholar on the Constitution made it clear that "[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).

While Story's wisdom applies, certainly, to the narrow issue of laws of nature, natural phenomena, and abstract ideas, the vast majority of all important innovations go beyond this narrow subset: Story's principle applies broadly, only muddled by *Deuterium* and other oddball opinions of the Federal Circuit. *See* § 3[c], *Deuterium Ghost at the Federal Circuit* (discussing *Deuterium Corp. v. United States*, 19 Cl.Ct. 624 (1990)(Rader, J.)).

Secondly, *Alice* says that for a claimed combination of elements the combination must represent something significantly more than being a patent on the ineligible concept itself. To understand this aspect of *Alice* two points should be made. *First*, it is up to the patent applicant to *define* his invention and to do so in a way to ascertain that his claim does not, indeed, block the ineligible concept itself. In a combination claim, the precise boundaries of that combination must be set forth, including any necessary *definition* of the claimed invention to ensure that the claimed invention is, indeed, more than a patent on the ineligible concept itself.

There is a rich body of Supreme Court case law covering the "all elements" rule that requires limitation of the scope of a combination claim for purposes of enforcement to embodiments that, in fact, have "all elements" as stated in the claim. The patentee holding a combination claim simply cannot extract one element, e.g., the abstract concept, and prevail against someone using that element apart from the combination: Such a combination claim can in no way shape or form block practice of the abstract concept (or other single element of the combination claim). See 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. *See* § 4[a], *The Invention as a Whole* (citing *Prouty v. Draper*, 41 U.S. (16 Pet.) 335 (1842); *Vance v. Campbell*, 66 U.S. (1 Black) 427, 429 (1861); *Eames v. Godfrey*, 68 U.S. (1 Wall.) 78, 79 (1864); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 337 (1879); *White v. Dunbar*, 119 U.S. 47 (1886)).

Third, the applicant must show that his claimed combination has an "inventive step". Ever since *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1851), established an "inventive step" as a requirement for patentability, it has been important that *any* innovation, to be patentable, must be more than an obvious modification of what was known before. While the Court in *Alice* speaks of an "inventive step", the only objective measure of an inventive step, today, is Section 103 of the *Leahy Smith America Invents Act* that narrows the definition of novelty to exclude the case where "the claimed invention was * * * available to the public before the effective filing date of the claimed invention[.]" 35 USC § 102(a)(1).

Fourth, the concern over "too much" protection is wrong, a departure from precedent. To the extent that there is a pioneer invention, then there can never be "too much" protection, consistent with a full disclosure of the invention and claim boundaries restricted to that which is nonobvious Indeed, there is a rich body of Supreme Court case law that makes the case for *broader* protection for basic inventions.

While a pioneer patent should generally have very broad *literal* coverage, due to the absence of prior art, the Court has gone further to award an even broader scope of protection under the doctrine of equivalents. *See* § 2[b][2], *Early Supreme Court Recognition of the Need for Broad Protection* (citing *Morley Sewing-Machine Co. v. Lancaster*, 129 U. S. 263 (1889); *Miller v. Eagle Mfg. Co*., 151 U. S. 186 (1894); *Cimiotti Unhairing Co. v. American Fur Refining Co*., 198 U.S. 399 (1905); *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 (1908)). The practical realities today make it difficult, at best, for a pioneer invention to be established against an entrenched technology making it all the more important for broad protection for an invention that is a sharp departure from the entrenched state of the art. *See* § 3[a][2], *Broad Patents "Promote the Progress of *** the Useful Arts."*

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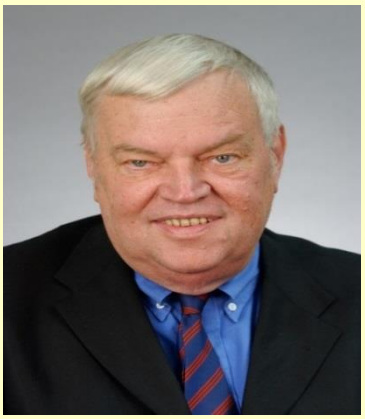

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