PATENT ELIGIBILITY: WHITHER *SEQUENOM*?

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SUMMARY OF CONTENTS

ABOUT THIS MONOGRAPH AND THE *SEQUENOM* PETITION

Sequenom, Inc. v. Ariosa Diagnostics, Inc., Supreme Court No. 15-1182, is the styling of the petition in the important challenge to the Federal Circuit denial of patent eligibility under 35 USC § 101to Sequenom's unique and most meritorious prenatal test.

The Court is expected to vote whether to grant *certiorari* before it adjourns for its Summer recess. If *certiorari* is granted, the patent community should take great interest in the appeal which would then be briefed in the coming months and set for argument most likely in late Fall or Early Winter.

Whether *certiorari* is granted in the first instance depends upon the *Question Presented* which petitioner has chosen to boldly state as follows:

"Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery."

Whether the Court *should* grant *certiorari* is a separate issue, given the unique approach taken by Petitioner in his *Question Presented.* The uniqueness is seen by contrasting Petitioner's approach with the issues that *could have been* chosen as explained at § 9, *The Sequenom Petition for Certiorari.*

Except for the present section, the *Preface* and the opening portions of of § 1, *Overview*, and § 9, *The Sequenom Petition for Certiorari* (both as identified in boxed text) this monograph repeats verbatim the text of the previous edition of March 1, 2016.

PREFACE

The law and practice relating to patent eligibility law are in a state of flux. This monograph is designed to provide practical guidance on how to draft a patent application in the wake of the confused and uncertain state of the law.

Last year this writer generated some controversy through his paper, *A Sequenom White Paper* (reproduced as an appendix), which questioned whether potential *amici* should participate at the petition stage in *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, Supreme Court No. 15-1182, *proceedings below sub nom Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). The *Question Presented* asks "[w]hether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery."

If *certiorari* is granted keyed to this bold statement of the *Question Presented*, petitioner will be hailed for its unique approach. Indeed, if *certiorari* is granted, the biotechnology and patent communities will certainly need to weigh in with *amici* efforts at the merits stage.

Legal issues particularly relevant to the *facts* of the *Sequenom* case (but not necessarily the *Question Presented*) are considered in detail at § 8, *En Banc-Worthy Issues Within Ariosa*. The unique approach taken with the *Question Presented* is manifested by the different approaches that could have been taken as explained at § 9, *The Sequenom Petition for Certiorari*.

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DETAILED TABLE OF CONTENTS

§ 8. *EN BANC*-WORTHY ISSUES WITHIN *ARIOSA*

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

§ 10. PTO PATENT-ELIGIBILITY EXAMINATION GUIDANCE

11. CLAIMING PATENT-ELIGIBLE SUBJECT MATTER

§ 1. OVERVIEW

Patent-*eligibility* of "compositions" and "manufactures" as well as software "process" patent-eligibility, all as defined in 35 USC § 101, are the focus of this monograph, particularly, the judicial *exceptions* to patent-eligibility in these categories such as the "abstract" elements of software innovations. Particular attention is also given to new compositions and the special relevance of the statutory exceptions to innovations in the fields of biotechnology and pharmaceuticals.

Of immediate concern is *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, Supreme Court No. 15-1182, the styling of a petition for *certiorari* where the *Question Presented* asks:

"Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery."

If the petition is granted, *Sequenom* may well turn out to be the most important patent-eligibility case in the than thirty-five years since *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), which had reopened a closing door to patent-eligibility under *Parker* v. *Flook*, 437 U.S. 584 (1978).

But, whether the result would be good or bad in large measure is keyed to the *Question Presented.* To the extent that the *Question Presented* opens new doors for the Court to explore, a merits decision could result in *continuation* of the dark pendulum swing that started with *Bilski v. Kappos*, 561 U.S. 593 (2010), and continued with *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), and 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)..

Should *certiorari* be denied, this would cap the damage of the *Ariosa* decision to the patent system at the level of the Federal Circuit. A test case at the Patent Trial and Appeal Board with facts similar to *Ariosa* could well provide the Federal Circuit with a chance to undo the damage created by its opinion in *Ariosa.*

If past is prologue, and *with an appropriate test case*, we may very well be on verge of a reversal of the trend that started with *Bilski*, much like what happened following a bleak anti-eligibility period starting with *Gottschalk* v. *Benson*, 409 U.S. 63 (1972); that continued through *Parker* v. *Flook*, 437 U.S. 584 (1978); the pendulum swung back to the historical common understanding of patent-eligibility then occurred *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); and *Diamond* v. *Diehr*, 450 U.S. 175 (1981), which started a thirty year period of Supreme Court pro-eligibility case law broken only with *Bilski*.

Of immediate concern to the patent community is the question whether *certiorari* will be granted based on the *Sequenom* petition.

Should the Court grant *certiorari*?

Will the Court grant *certiorari?*

The "should" question depends upon whether this case *in the posture of the Question Presented* represents a solid test vehicle to reverse the trend from *Mayo* and *Myriad.*

The "will" question to a great extent will depend upon whether industry files plural *amici* briefs *at the petition stage*. The act of filing such briefs would push the needle toward grant of *certiorari.* Or, by *refraining from amici participation* at

the petition stage, this would push the needle toward denial of review. (Of course, it is another matter altogether whether *amicus* participation is warranted at the merits stage, which would only become an issue if *certiorari* is granted.)

As noted at the beginning of this monograph, *About this Monograph and the Sequenom Petition*, page 3, the text of this monograph is essentially taken verbatim from the previous version (March 1, 2016). In this chapter, only the beginning paragraphs, above, have been added, while the remainder of this chapter is taken *verbatim* from the previous version.

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.

The Starting Point: Fresh Legal Research

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 excepts 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 Corp. v. CLS Bank International*, 134 S. Ct. 2347, 2354 (2014)(quoting the *Myriad* case, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2116 (2013)), 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[.]" *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).

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). Those 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* – with *Mayo v. Prometheus* and *Myriad* sandwiched between these cases.

This current period of fifteen years – and counting – 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 patent-eligibility. (It is pure mythology to say that this body of case law has roots either in the early nineteenth century case law of England or early American case law: It is simply nonsense to say that the *Bilski* to *Alice* run of case law is based upon "150 years" of precedent.)

The Less than 10 Year *Benson* to *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 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 which dates back to the early days of the country with pronouncements by legendary Justice Joseph Story. *See, e.g., 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 (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.'").

The *Bilski* Argument of "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 to 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 more 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)(quoting Metabolite, supra); 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 has 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)).

Ten Patent Drafting Rules for a "Patent-Eligibility" Test Case

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 actual is *unpatentable* for one or more reasons.

Some of the patent-eligibility cases have, in fact, raised issues of *patentability* that were decisive in deny 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 are 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 combination 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. Although the case was incorrectly decided, the *Ariosa* factual pattern represents a text book case where there is no motivation shown in the prior art to put together the combination…

Rule 8: Recognition of a Problem without a Solution

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

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 define 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 *In re Bergy*, 596 F.2d 952, 966 (CCPA 1979)) was critical. Today, the matter is not as simple as 1980 because the *right* to experiment "on" a patented invention that was clear in 1980 is now muddled with a series of Federal Circuit cases that in holding or dicta suggest the patent right leaves no room for a right to experiment "on" the 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.); *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.)).

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 and what the successor court did is in sharp contrast to 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 near future, but only upon the resignation of the incumbent Under Secretary of Commerce 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 the 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." It is unmistakably clear the Under Secretary has

abdicated her leadership responsibilities in the provision of the patent-eligibility guidance, given 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 leadership in the Patent Office in this 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 corporate patent leadership position leading up to her present 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".

While the preceding discussion may suggest a test case is necessary, and that is true from the standpoint that *someone* will have to bear the load of such a case, it is not in the end necessary for an individual applicant to do so: But, the application should be prepared and prosecuted under the case law so that when a test case *is* presented and won, the applicant will be in a position to piggyback off the result.

§ 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 who leads the Patent Office – and is expected to do so until a new Administration takes over the White House in 2017.

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.

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

First, "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), that 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 shortty 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[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 when there certainly will be a new Under Secretary of Commerce in charge of the Patent Office. Thus, "today" for all practical purposes will be a date at some point not earlier than 2017 when we will have fresh leadership at the Office.

In addition to presenting the patent application in the manner suggested in the previous section, 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" independent of the particular element with an "abstract" feature or "natural" derivative that remains in the claim.

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).

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

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

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

Prior to *Bilski* the last Supreme Court holding denying patent-eligibility was in *Parker v. Flook*, 437 U.S. 584 (1978), which also employed the same

mythology: "'A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.' *Le Roy v. Tatham*,[55 U.S. (14 How.) 156, 175 (1853)]. Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." [*Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)]." *Parker v. Flook*, 437 U.S. at 589.

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

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

§ 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). 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, 5*96 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 174-5.")

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

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

"A new property discovered in matter, when practically applied, in the construction of a useful article of commerce or manufacture, is patentable; but the process through which the new property is developed and applied, must be stated, with such precision as to enable an ordinary mechanic to construct and apply the necessary process. This is required by the patent laws of England and of the United States, in order that when the patent shall run out, the public may know how to profit by the invention. *It is said, in the case of the 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 pencil *was* directed to patentable subject matter was emphasized when the case returned to the Supreme Court several years later: "[The invention's] application to the development and employment of a new property of lead made a new and patentable process. *See Le Roy v. Tatham*[, 63 U.S. (22 How.) 132 (1859)]." *Id.*

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

A Supreme Court case from the same century, *Busell Trimmer Co v. Stevens*, 137 U.S. 423 (1890)(Lamar, J.). *See also* Professor Jeffrey A. Lefstin, *Inventive*

Application: A History, 67 Fla. L. Rev. 565, 594-96 (2015). As explained in *Bussell Trimer:*

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

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

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

The3holding 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.

Echoing a 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 that having a vintage of more than 165 years.

The leading patent scholar-practitioner at the time of *O'Reilly v. Morse* provides a contemporaneous view of the case:

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

Indeed, formularies are of very little use in this branch of the law; for, to use an expression of Lord Kenyon's, 'there is no magic in words,' as mere words. Words which mean things, and which relate to things, are the important matters of judicial cognizance in determining the meaning and operation of these instruments.

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

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

§ 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] 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); *The Real Story of O'Reilly v. Morse* (citing 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). Earlier, in the same case *en banc Bilski* case at the Federal Circuit Circuit Judge Mayer made a parallel argument:

'[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 plural examples in the case of the "150 years" of *stare decisis* concerning patent-eligibility where this is not the case:

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 ourt 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 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).

♦ ♦ ♦ ♦ ♦ ♦

§ 3. A PATENT DOES NOT "PREEMPT" RESEARCH

It is axiomatic as part of the evolution of nineteenth century patent law that to "Promote the Progress of ** the Useful Arts", the public has a right to experiment *on* the patented invention. *See* § 3[a], *Constitutional Right to Experiment on a Patented Invention.* (Confusion has been generated by the fact that it is only a right to experiment *on* a patented invention that is free from patent infringement, as opposed to experimentation *with* a patented invention that has nothing to do with preemption of research. This distinction is perhaps best explained by Professor Mueller. *See* 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)).

In the formative years of American patent law there never was a concern that broad – or *any* – patents would "preempt" research. This had everything to do with the Story line of case law which established a *right* to experiment on a patented invention: In other words, the patent right does not extend to block follow-on research *on* the invention. *See* § 3[a][1], *The Story Line of Case Law.* Indeed, "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 useful arts.'" *Id.* (quoting *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).)

The message concerning a right to experiment *on* a patented invention has been lost on at least some members of the Federal Circuit, in large measure stemming from the strident and unequivocal denial of this right by a now resigned

member of the court who has stated that "the Patent Act leaves no room for any *** experimental use excuses for infringement. *** [A]n experimental use excuse cannot survive." § 3[c], *Deuterium Ghost at the Federal Circuit* (quoting *Embrex v. Service Eng'g Corp*., 216 F.3d 1343, 1352 (Fed.Cir.2000) (Rader, J., concurring)).

The preemption argument is not new, but has permeated the Section 101 case law for the past generation. *See* § 3[b], "*Research Preemption" Confusion in Mayo* (quoting extensively from *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) (citations omitted).

A former and recently resigned member of the court has said that "the Patent Act leaves no room for any de minimis or experimental use excuses for infringement. *** [N]o room remains in the law for a de minimis excuse. *** [A]n experimental use excuse cannot survive." *See* § 3[c], *Deuterium Ghost at the Federal Circuit* (quoting *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1352-53 (Fed.Cir. 2000) (Rader, J., concurring)).

As an example of the need for *en banc* resolution of the issue of the right to experiment *on* a patented invention, one need look no further than the majority opinion in the *Ariosa* case which uncritically accepts, without discussion, the flawed premise that patents *do* preemption research, and thus adopts the view of the now resigned former member of the court in *Embrex*:

"The Supreme Court has made clear that the principle of preemption is the basis for the judicial exceptions to patentability. *Alice* [*Corporation Pty. Ltd. v. CLS Bank International*, 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 Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, __, slip op. at 14 (Fed. Cir. 2015), *further proceedings pending sub nom Sequenom v. Ariosa Diagnostics,* Supreme Court No. 15A871.

(The *Ariosa* opinion is doubly flawed as to its discussion of "preemption" because the Sequenom invention in the *Ariosa* case claims neither any DNA nor any method of use of DNA so there is nothing to "preempt" in the way of the DNA set forth in the claim. Indeed, the *known* DNA in the Sequenom invention is the object of *identification* for its presence or absence which has absolutely nothing to do with any possible "preemption" of the use of any DNA.)

Unless and until the Federal Circuit grants *en banc* review to clarify that there *is* a right to experiment *on* a patented invention (as explained by Professor Mueller) the confusion in the law of patent-eligibility will continue unabated.

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

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

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

Bilski, 130 S.Ct. at 3236.

See § 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":

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 patetnt 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.*

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

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

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

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

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

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

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 Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012) (citations omitted)

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

We have "long held that [35 USC § 101] contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable." *Mayo*, 132 S.Ct. at 1293)[ ]. Rather, " 'they are the basic tools of scientific and technological work' " that lie beyond the domain of patent protection. *Id.*, 132 S.Ct. at 1293. As the Court has explained, without this exception, there would be considerable danger that the grant of patents would "tie

up" the use of such tools and thereby "inhibit future innovation premised upon them." *Id.*, at ——, 132 S.Ct., at 1301. This would be at odds with the very point of patents, which exist to promote creation. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)(Products of nature are not created, and " 'manifestations ... of nature [are] free to all men and reserved exclusively to none' ").

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

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 the *Deuterium* is the unequivocal and total denial in the *Myriad* case of any third party right to use a patented invention issued by the now retired Vice President of SmithKline Beecham Corporation; 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.

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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 authored doubled down on his denial of any experimental use exception to patent infringement in the *Embrex* case where he ridiculed the 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). He adds 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.

§ 3[c]. *Deuterium* Ghost at the Federal Circuit

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 specification were met and not to design around or otherwise experiment "on" the patented invention. In *Madey,* a patented laboratory tool was used to conduct research and not to study the laboratory tool itself. The use of the patented invention would be more akin to the situation where a microscope is patented and the accused infringement is the use of the microscope to study a subject – an experimentation *with* the microscope, as opposed to studying the microscope itself, to, for example, improve the microscope or understand its operation, an experimentation *on* the microscope.

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

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

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

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

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.)

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

§ 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:

m"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 – 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).

♦ ♦ ♦

§ 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 – and possessed "invention" – or an "inventive" feature, as from a body of case law that developed through case law beginning in the mid-nineteenth century that was codified in the 1952 Patent Act as 35 USC § 103. This common understanding was shattered by Supreme Court decisions in *Gottschalk* v. *Benson*, 409 U.S. 63 (1972); *Parker* v. *Flook*, 437 U.S. 584 (1978), but the pendulum swung back to the historical common understanding with *Diamond v. Chakrabarty,* 447 U.S. 303 (1980); and *Diamond* v. *Diehr*, 450 U.S. 175 (1981). Thirty years after *Benson* uncertainty returned with *Gottschalk* v. *Benson*, 409 U.S. 63 (1972); *Parker* v. *Flook*, 437 U.S. 584 (1978).

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

"**Anatomy of the Patent Statute**

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

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

{**"Invention" Changed to Nonobviousness in the 1952 Patent Act**}

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

"The Revised Statutes of 1874, which contained the primary patent statutes revised and codified in 1952, lumped most of the conditions for patentability in a single section, § 4886, as did all of the prior statutes back to the first one of 1790. The 1952 Act divided that statute up into its logical components and *added* the nonobviousness requirement, which until then had been imposed only by court decisions. This attempt at a clearcut statement to replace what had been a

hodgepodge of separate enactments resulted in a new and official Title 35 in the United States Code with three main divisions. Part I pertains to the establishment and organization of the PTO. Part II, here involved, covers patentability of inventions and the grant of patents. Part III relates to issued patents and the protection of the rights conferred by them.

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

"Sec. 100 Definitions
"Sec. 101 Inventions patentable if they qualify
"Sec. 102 Conditions for patentability; novelty and loss of right to patent
"Sec. 103 Conditions for patentability; non-obvious subject matter

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

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

{"First Door", Section 101 Patent-Eligibility}

"The first door which must be opened on the difficult path to patentability is § 101 (augmented by the § 100 definitions), quoted supra p. 956. The person approaching that door is *an inventor*, whether his invention is patentable or not. There is always an inventor; being an inventor might be regarded as a preliminary legal requirement, for if he has not invented something, if he comes with something he knows was invented by someone else, he has no right even to approach the door. Thus, section 101 begins with the words 'Whoever invents or discovers,' and since 1790 the patent statutes have always said substantially that. Being an inventor or having an invention, however, is no guarantee of opening even the first door. What *kind* of an invention or discovery is it? In dealing with the question of kind, as distinguished from the qualitative conditions which make the invention patentable, § 101 is broad and general; its language is: 'any * * *

process, machine, manufacture, or composition of matter, or any * * * improvement thereof.' Section 100(b) further expands 'process' to include 'art or method, and * * * a new use of a known process, machine, manufacture, composition of matter, or material.' If the invention, as the inventor defines it in his claims (pursuant to § 112, second paragraph), falls into any one of the named categories, he is allowed to pass through to the second door, which is § 102; 'novelty and loss of right to patent' is the sign on it. Notwithstanding the words 'new and useful' in § 101, the invention is not examined under that statute for novelty because that is not the statutory scheme of things or the long-established administrative practice.

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

"The PTO, in administering the patent laws, has, for the most part, consistently applied § 102 in making rejections for lack of novelty. To provide the option of making such a rejection under either § 101 or § 102 is confusing and therefore bad law. Our research has disclosed only two instances in which rejections for lack of novelty were made by the PTO under § 101, *In re Bergstrom,* 427 F.2d 1394 (CCPA 1970); *In re Seaborg,* 328 F.2d 996 (CCPA 1964). In *In re Bergstrom* we in effect treated the rejection as if it had been made under § 102, observing in the process that 'The word `new' in § 101 is defined and is to be construed in accordance with the provisions of § 102.' 427 F.2d at 1401.

* * *

{"Second Door", Section 102 Novelty}

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

"Section 102 also contains other conditions under the heading 'loss of right' which need not be considered here. An *invention* may be in a statutory category and not patentable for want of *novelty,* or it may be novel and still not be patentable because it must meet yet another condition existing in the law since 1850 when *Hotchkiss 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, 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 Systems, Inc.* v. *Duracraft Corp.*, 58 F.3d 1498, 1500 (10th Cir. 1995) ("product

configuration is a significant inventive component of an invention"); cf. *Quanta*, 553 U.S. at 634 ("common and noninventive"); *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 277 (1976) (invention unpatentable because "[t]he only claimed *inventive feature*" falls short of the test for nonobviousness under 35 USC § 103) (emphasis added).

The several Circuit Courts of Appeal have also referred to an "inventive concept" in lieu of the statutory term nonobviousness. The Third Circuit spoke of patentability in terms of subject matter being "inventive", and as having an "inventive concept": "Since *Miller v. Eagle*[, 151 U.S. 186 (1894)], courts have repeatedly ruled that an inventor's separate applications embodying the same *inventive concept* afford proper bases for the issuance of separate patents at different times only if one of them also embodies an additional *inventive concept* not present in the other. In other words, *the difference between the claims of the two applications must itself be inventive*." *Wahl v. Rexnord, Inc.*, 624 F.2d 1169 1178 (3rd Cir. 1980)(quoting *Pierce v. Allen B. DuMont Laboratories, Inc.*, 297 F.2d 323, 327 (3d Cir. 1961))(emphasis added). *See also Forbro Design Corp. v. Raytheon Co.*, 532 F.2d 758, 765(1st Cir.1976)("Dr. Kupferberg had deposed that the *inventive concept* was contained in the first few paragraphs of the patent[.]")(emphasis added); *Olympic Fastening Systems, Inc. v. Textron, Inc.*, 504 F.2d 609, 616 (6th Cir.1974)(The witness Ketchum testified … that the extent to which the [feature] is not a part of the *inventive concept* of the Gapp patent.")(emphasis added); *Groen v. General Foods Corp.*, 402 F.2d 708, 711 (9th Cir. 1968)("[A]ppellants rely principally upon the alleged *inventive concept* involved in the combination of steps set forth in the claim."); *Ellipse Corp. v. Ford Motor Co.*, 452 F.2d 163, 167 (7th Cir. 1971)("This purported [limitation] is *the inventive concept* of the pump and distinguishes it from the prior art.")(emphasis

added); *McCullough Tool Co. v. Well Surveys, Inc.*, 343 F.2d 381, 397 (10th Cir. 1965)("The asserted *inventive concept* of the patent in suit is an alleged new combination of elements having a new mode of operation[.]")(emphasis added).

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

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

§ 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).

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

opponents to software patent protection, the road to legislative change is at best uncertain.

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

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

This section considers drafting options and reasons to continue to prepare and at least permit publication of the application to create 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 door opening to *patentability* that is limited to inventions that meet the requirements of Sections 102, 103 and 112.

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

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

Whether such *application* as in *Diehr* is *patentable* depends upon whether it meets the statutory *patentability* requirements of sections 102, 103 and 112. The

Bilski invention under the Court's analysis clearly fell short of passing patentability muster. The same can be said for the invention is *Alice Corp. Pty. Ltd. v. CLS Bank Int'l,* 134 S. Ct. 2347, 2352 (2014)("merely requiring generic computer implementation fails to transform that abstract idea into a patent-eligible

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

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

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

In. *Diehr*, although the claim employed what is described as a 'well-known' mathematical equation, there were additional steps included in the claim: "These additional steps, we recently explained, 'transformed the process into an inventive application of the formula." *Alice,* 134 S.Ct. at 2358 (citation omitted). Or, "[i]n other words, the claims in *Diehr* were patent eligible because they improved an

existing technological process, not because they were implemented on a computer." *Alice*, 134 S.Ct. at 2358.

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

§ 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.*)

invention.").

§ 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] An Improper *Per Se* Denial of Patentability

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."

"[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.

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§ 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 Bergy,* 596 F.2d at 966 ("[N]o formula, algorithm, or law of nature is involved, and there has been no rejection on prior art of any kind

… [B]oth the examiner and the Board of Appeals expressly stated that no references evidencing prior art have been relied on or applied.")

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

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

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

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

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

"[Dr. Chakrabarty]'s micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.' *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887). The point is underscored dramatically by comparison of the invention here with that in *Funk* [*Brothers Seed Co. v. Kalo Inoculant Co.*, 333

U.S. 127 (1948)]. There, the patentee had discovered that there existed in nature certain species of root-nodule bacteria which did not exert a mutually inhibitive effect on each other. He used that discovery to produce a mixed culture capable of inoculating the seeds of leguminous plants. Concluding that the patentee had discovered 'only some of the handiwork of nature,' the Court ruled the product nonpatentable:

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

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

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

The statement that Dr. Chakrabarty's invention has "markedly different characteristics", is a confirmation of the scientific achievement of Dr. Chakrabarty and not a statement setting the minimum standards for patent eligibility. The fact that the *Chakrabarty* invention has "markedly different characteristics" manifests the fact that the invention is far above the minimum standard of an "inventive" or nonobvious feature. Thus, it is only necessary to establish nonobviousness by

showing difference in properties for a claimed composition if there is a case of *prima facie* obviousness.[*]

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

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

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

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

more than merely incidental changes to the naturally occurring product. In cases such as this one, in which the applicant claims a composition of matter that is nearly identical to a product of nature, it is appropriate to ask whether the applicant has done 'enough' to distinguish his alleged invention from the similar product of nature. Has the applicant made an 'inventive' contribution to the product of nature? Does the claimed composition involve more than 'well-understood, routine, conventional' elements?")(emphasis added)

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

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

"In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, [333 U.S. 127 (1948)], the Court considered the validity of a patent to one Bond and the alleged infringement of a number of the patent's product claims. The subject matter involved certain naturally occurring bacteria of the genus *Rhizobium* which infect the roots of leguminous plants and form nodules thereon hence enabling the plants to transform atmospheric nitrogen into organic nitrogenous compounds necessary for plant growth. It was well known that each species of these naturally occurring bacteria would only infect certain species of leguminous plants. Attempts (prior to Bond's work) to produce a useful mixture of bacteria, which farmers could use upon planting more than a single variety of plant, were unsuccessful. When mixed, different species of *Rhizobium* bacteria exhibited a mutually inhibiting effect and no suitable mixture had, therefore, been produced. Bond discovered that certain strains of the bacteria were not mutually inhibitive and he produced mixtures of the

Rhizobium bacteria which mixtures were capable of inoculating multiple varieties of plants. Bond was granted a patent on his discovery. The Supreme Court found the following claim to be representative of Bond's invention:

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

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

" 'We do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable. We have here only product claims. Bond does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. See *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1853). The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. 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).

§ 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." [*]

§ 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

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[*] Claim 31, rewritten in independent form:

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

Claim 31. "The innoculated medium of claim 30 wherein the carrier medium is straw."

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).

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

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

Indeed, the Court recognizes that Bond's mixture is a "new and different *composition*":

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

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

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

Leading up to *Chakrabarty*, it was understood that compositions based upon natural products have long been considered both patent-eligible under Section 101 efand "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.

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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, whereas today more and more cancers are treatable and in some areas the prognosis for recovery outweighs the alternative. Yet, specific cancer treatments remain elusive as only one out of literally thousands of compounds has true efficacy in humans and many cancers remain untreatable.

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§ 8. *EN BANC*-WORTHY ISSUES WITHIN *ARIOSA*

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

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

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

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

"In applying the second part of the test, the Supreme Court in *Mayo* discounted, seemingly without qualification, any '[p]ost-solution activity that is purely conventional or obvious,' *id*. at 1299 (original alterations omitted). This was unnecessary in *Mayo*, because doctors were already performing in combination all

of the claimed steps of administering the drug at issue, measuring metabolite levels, and adjusting dosing based on the metabolite levels, *id*.

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

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

"It is hard to deny that [the] invention is truly meritorious. Prior to the '540 patent, prenatal diagnoses required invasive methods, which 'present[ed] a degree of risk to the mother and to the pregnancy.' *Id*. at col.1 ll. 16—17. The available 'techniques [we]re time-consuming or require[d] expensive equipment.' *Id*. at col.1 ll.17—37. Dr. Mark Evans testified that 'despite years of trying by multiple methods, no one was ever able to achieve acceptable success and accuracy.' In a groundbreaking invention, Drs. Lo and Wainscoat discovered that there was cell-free fetal DNA in the maternal plasma. The Royal Society lauded this discovery as 'a paradigm shift in non-invasive prenatal diagnosis,' and the inventors' article describing this invention has been cited well over a thousand times. The commercial embodiment of the invention, the MaterniT21 test, was the first marketed non-invasive prenatal diagnostic test for fetal aneuploidies, such as Down's syndrome, and presented fewer risks and a more dependable rate of

abnormality detection than other tests. Unlike in *Mayo*, the '540 patent claims a new method that should be patent eligible. While the instructions in the claims at issue in *Mayo* had been widely used by doctors—they had been measuring metabolites and recalculating dosages based on toxicity/inefficacy limits for years—here, the amplification and detection of [cell-free fetal DNA] had never before been done. The new use of the previously discarded maternal plasma to achieve such an advantageous result is deserving of patent protection. *Cf*. Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 Yale L.J. Online 341, 343-44 (2013) (noting that despite *Mayo*'s declaration that a claim to 'a new way of using an existing drug' is patentable, *Mayo*, 132 S. Ct. at 1302, it is unclear how a claim to new uses for existing drugs would survive *Mayo*'s sweeping test).

"In short, [the] invention is nothing like the invention at issue in *Mayo*. [The patentees] 'effectuate[d] a practical result and benefit not previously attained,' so its patent would traditionally have been valid. *Le Roy v. Tatham*, 63 U.S. 132, 135-36 (1859) (quoting *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 *en banc*-worthy:

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

Two critical shortcomings are apparent from *Ariosa*. Patent-eligibility should be determined by (a) first reading an entire claim *as a whole* to give weight to "all elements" of the claim to determine the metes and bounds of protection; and (b) then determining whether the *overall claimed combination*, is "inventive", which should end the inquiry. In this latter regard concerning the *overall claimed combination* it is often the *combination* that is "inventive", whereas the component

elements, individually, may all lack patent-eligibility, standing *in vacuo* apart from the claimed combination.

§ 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 MaterniT21 test, was the first

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

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

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

§ 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: Is there "inventive" subject matter – subject matter that is thus "nonobvious" under 35 USC § 103 – yet can such "inventive" subject matter lack patent-eligibility under 35 USC § 101?

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

§ 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, i*nventive* application of the law." *Mayo*, 132 S. Ct. at1294; 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.

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

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

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

patent law, that the claim of a combination is not infringed if any of the material parts of the combination are omitted. ***").

The quoted cases are merely illustrative of the many "all elements" cases from the nineteenth century that include, *inter alia*, *Vance v. Campbell*, 66 U.S. (1 Black) 427, 429 (1861); *Eames v. Godfrey*, 68 U.S. (1 Wall.) 78, 79 (1864); *Gould v. Rees*, 82 U.S. (15 Wall.) 187 (1872); *Dunbar v. Myers*, 94 U.S. (4 Otto) 187, 202 (1876); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 335-37 (1879); *Case v. Brown*, 69 U.S. (2 Wall.) 320, 327-28 (1864); *Gill v. Wells*, 89 U.S. (22 Wall.) 1, 26-30 (1874); *Fuller v. Yentzer*, 94 U.S. (4 Otto) 288, 297 (1876); *Gage v. Herring*, 107 U.S. (17 Otto) 640, 648 (1882); *Fay v. Cordesman*, 109 U.S. 408, 420-21 (1883); *Rowell v. Lindsay*, 113 U.S. 97, 102 (1885); *Sargent v. Hall Safe & Lock Co.*, 114 U.S. 63, 86 (1885); *Brown v. Davis*, 116 U.S. 237, 252 (1886); *Yale Lock Mfg. Co. v. Sargent*, 117 U.S. 373, 378 (1886); *McClain v. 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 that 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] T**he "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. *See* § 3[c], *Deuterium Ghost at the Federal Circuit* (discussing *Deuterium Corp. v. United States*, 19 Cl.Ct. 624 (Cl.Ct.1990)(Rader, J.); *Embrex v. Service Eng'g Corp.*, 216 F.3d 1343 (Fed.Cir.2000) (Rader, J., concurring); *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed.Cir.2002)(Gajarsa, J.)).

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

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

> [T]he preemption concern [ ] undergirds our §101 jurisprudence. Given the ubiquity of computers, see 717 F.3d [1269, 1286 (Fed. Cir. 2013)] (Lourie, J., concurring), wholly generic computer implementation is not generally the sort of 'additional featur[e]' that provides any 'practical assurance that the process is more than a drafting effort designed to monopolize the [abstract idea] itself.' [quoting *Mayo*]
>
> The fact that a computer 'necessarily exist[s] in the physical, rather than purely conceptual, realm,' Brief for Petitioner 39, is beside the point. There is no dispute that a computer is a tangible system (in §101 terms, a 'machine'), or that many computer-implemented claims are formally addressed to patent-eligible subject matter. But if that were the end of the §101 inquiry, an applicant could claim any principle of the physical or social sciences by reciting a computer system configured to implement the relevant concept. Such a result would make the determination of patent eligibility 'depend simply on the draftsman's art,' [*Parker v. Flook*, 437 U.S. 584, 593 (1978),] thereby eviscerating the rule that ' '[l]aws of nature, natural phenomena, and abstract ideas are not patentable,' ' [quoting *Myriad*]

But, the invention *as claimed* in *A* provides absolutely no preemption of the DNA involved in the claimed invention. There is no more preemption of the use of that DNA in the future as that very DNA of the claimed invention is *neither* claimed *nor* is a use of the DNA claimed: The DNA is merely *identified* in the claimed invention. To say that the claim in *Ariosa* "preempts" the use of the DNA would be akin to saying that identification of a biological sample under a microscope is "preempted" for future use, merely because the method of identification is patented. For example, if identifying a particular biological

sample required a unique *staining* of that sample before inspection under the microscope, if nonobvious, one could obtain the method of identifying the biological sample by first staining the sample prior to evaluation under the microscope.

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

♦ ♦ ♦

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

Sequenom, Inc. v. Ariosa Diagnostics, Inc., Supreme Court No. 15-1182, is the styling of a petition for *certiorari* where the *Question Presented* asks:

"Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery."

As noted at the beginning of this monograph, *About this Monograph and the Sequenom Petition*, page 3, the text of this monograph is essentially taken verbatim from the previous version (March 1, 2016). Except for the text above, the remainder of this chapter is taken verbatim from the previous version..

Because of the peculiar manner of argument by the patentee that unnecessarily invokes patent-eligibility issues relating to DNA, grant of *certiorari* would be an at best mixed blessing. A possible *affirmance* of the Federal Circuit would represent a further step to ossify and perhaps even expand the negative rulings in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), and the *Myriad* case, *Ass'n for Molecular Pathology v. Myriad Genetics., Inc.*, 133 S. Ct. 2107 (2013).

If the patentee reprises its line of argument used at the Federal Circuit it will seek to distinguish a "biotechnology" invention from *Mayo* and the *Myriad* case. If, indeed, this pathway is followed, *and if certiorari* is granted, then it will be important to have merits *amici* briefing to attempt to limit the scope of *Mayo* and *Myriad*. But, short of grant of *certiorari*, it is questionable whether industry

should support grant of *certiorari*, to take the unnecessary chance to open the door to a monumental, anti-patent merits decision.

This is *not* a case about a composition or method relating to a "biotechnology" invention, any more than an electron microscope used to analyze cells is a "biotechnology" invention. Rather, like a "microscope" used to identify characteristics within its view, here, the invention is simply one to determine whether particular, already known and characterized DNA is *present* in a blood sample.

§ 9[a] The Differing Views within the Circuit

If the *Sequenom* Supreme Court petition follows the unsuccessful path of the arguments the patentee made at the Federal Circuit then this case has unnecessarily been transformed into a sideshow to *Mayo* and *Myriad* to reargue points relating to claims to DNA, *per se*, or a method of using DNA. Indeed, this was the *misunderstanding* of the case within the court, both by the panel majority, *Ariosa Diagnostics, Inc. v. Sequenom, Inc*., __ F.3d __, __ slip op. at 3 (2015) (Reyna, J.)("[T[he [ ] patent claims certain methods of using cffDNA."), as well as by some members of the en banc court in the denial of rehearing *en banc*, *Ariosa Diagnostics , Inc. v. Sequenom, Inc.*, __ F.3d __, __ slip op. at 11 (Dec. 2, 2015) (Lourie, J., joined by Moore, J., concurring in den. reh'g en banc)("[T]his is, apparently, *a novel process* and that is what patents are intended to incentivize and be awarded for.")(emphasis added); *id.*, __ F.3d __, __ slip op. at 14 (Dyk, J., concurring in den. reh'g en banc) (quoting *Mayo*, 132 S. Ct. at 1294, quoting *Parker v. Flook*, 437 U.S. 584, 594 (1978))("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…"). Cf. the

Myriad case, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1354 (Fed. Cir. 2012)(Bryson, J., concurring in part and dissenting in part) ("The use to which the genetic material can be put, i.e., determining its sequence in a clinical setting, is not a new use; it is only a consequence of possession.").

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][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.

* * *

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[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 theclaims 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, J., 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

While the Federal Circuit is bound to follow the law as set forth by the Supreme Court, it should not broadly read *dicta* to the point that such *dicta* is in conflict with the *holdings* of prior Supreme Court precedent.

In his concurrence in denial of rehearing en banc – 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).

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.

In any event, and as explained at § 8[c], *Research "Preemption" as Basis to Deny Patent-Eligibility*, 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.

See § 3[c], *Deuterium Ghost at the Federal Circuit* (discussing *Deuterium Corp. v. United States*, 19 Cl.Ct. 624 (Cl.Ct.1990)(Rader, J.); *Embrex v. Service Eng'g Corp*., 216 F.3d 1343 (Fed.Cir.2000) (Rader, J., concurring); *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed.Cir.2002)(Gajarsa, J.)).

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

> 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.

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

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

§ 9[f] Rethinking *Sequenom* at the Supreme Court : A Fresh Approach

Sequenom, Inc. v. Ariosa Diagnostics, Inc., is the styling of the expected *certiorari* petition from *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __ (Fed. Cir. Dec. 2, 2015)(Order denying en banc review), *panel proceedings*, 788 F.3d 1371 (Fed. Cir. 2015). This section takes a fresh approach to the issues in the case and how the case *should* be considered at the Supreme Court:

An appellate tribunal quite naturally looks at an appeal from the standpoint of the arguments presented by the appellant in its opening brief. After all, the burden rests with the appellant to show why the decision below is wrong. In this way, the patentee in *Ariosa* at the Federal Circuit let the court fall into the trap of a step by step analysis focusing neither on the invention *as a whole* nor on the principal basis for the denial of patent-eligibility in the *Bilski* through *Alice* line of case law, that granting certain patents "preempts" future research and use of particular subject matter. *Bilski* v. *Kappos*, 561 U.S. 593 (2010)(software); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)(diagnostic method); the *Myriad* case, *Ass'n for Molecular Pathology v. Myriad Genetics., Inc.*, 133 S. Ct. 2107, 2116 (2013)(DNA, *per se*); *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014)(software).

A fresh approach is needed. The issue should be framed in the following manner:

Where an invention is to a method to *detect* the existence of particular DNA in the fetal bloodstream through the nonobvious choice to draw blood from the arm of the mother (instead of prior art womb-invasive amniocentesis), does the fact that the object of the testing is the recognition of *known* and hence unpatentable DNA, does the fact that DNA, *per se*, may lack patent-eligibility deny patent-eligibility of the DNA testing method, particularly where there is absolutely no "preemption" of the use of fetal DNA in any way, shape or form?

§ 9[f][1] Consideration of the Invention *as a Whole*

The Federal Circuit decision fails to look to the invention *as a whole*, a requirement 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)."

§ 4[a], *The Invention "As a Whole"* (quoting the *Adams Battery* case, *United States v. Adams*, 383 U.S. 39, 48-49 (1966); *see also id.* (citing *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).

§ 9[f][2] A "Microscope" to *Identify* Previously Known DNA

The better approach is to view the invention in the coming *Sequenom* petition *as a whole* whereupon one sees an invention which can be compared to a "microscope", a "ruler", a "laser detection device"… or a simple blood test performed in a doctor's office to see whether a subject has a particular disease or other abnormality. The instant invention is most comparable to a simple blood test drawn from the arm. There are undoubtedly thousands of improvements which have been made over the last century in conventional blood testing and none has been subject to the absurd notion that it lacks patent-eligibility under 35 USC § 101. In the context of this case, all of the "microscope"-like inventions have in common the *measurement* or *identification* of some DNA or other matter found in

a bodily fluid. The *measured* or *identified* substance is the object of the testing, but that object is not in any way patented through use of the "microscope" nor is that object's use for future research blocked by the test of the "microscope".

In the invention of the *Sequenom* petition, the claimed invention *as a whole* provides a test of a pregnant mother's *blood sample* drawn from the arm, just as one runs any conventional blood test in a doctor's office. But, this is not like any other blood test, one that is a fabulous breakthrough because the prior art had no conception that this blood test could be operative to test for fetal DNA. First of all, there was no recognition that fetal DNA was present in the maternal blood stream: Indeed, the amount of such fetal DNA in the bloodstream was *de minimis* in terms that there is not enough of the substance to permit its identification. Secondly, coupled with the recognition by the inventors that there *is* a trace amount of fetal DNA in the bloodstream, the invention includes the recognition that this trace amount of DNA could be *amplified* by the surprising breakthrough of Dr. Cary Mullis' Nobel Prize-winning polymerase chain reaction (PCR) technology. While one could consider, *arguendo*, that the application of Mullis' technology would have been obvious had this occurred immediately after his Nobel Prize-winning discovery, a generation went by after his discovery until the present invention was created.

§ 9[f][3] Breakthrough Technology that is, *a Fortiori*, "Inventive"

There can be no doubt in any way, shape or form about the breakthrough nature of the instant invention: Imagine, to permit a fetal DNA test which involves drawing blood from a pregnant mother's arm *versus* the conventional prior art method of womb-invasive amniocentesis to extract fluid from the womb! Without a doubt, the invention in this case is a true breakthrough and, *a fortiori,* one that is manifestly nonobvious under 35 USC § 103. *See* § 9[c], *"Inventive" Subject Matter under the "All Elements" Rule.*

§ 9[f][4] There is No "Preemption" Issue in this Case

Tthere is absolutely zero preemption of any kind concerning the object of the blood test in this case: The only object of prenatal testing is to *identify* the presence or absence of certain known DNA. There is no patent protection for any such DNA as to the DNA, *per se*, nor to its use or to its manufacture. Zero.

But, "preemption" is the basic ground to deny patent-eligibility of categories of inventions as explained in detail in § 3[b], *"Research Preemption" Confusion in Mayo.* As stated in that section, *Mayo* quite clearly pins denial of patent-eligibility to "preemption":

> [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.
>
> * * *
>
> * * * [D]o 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)

Later cases reprise the *Mayo* preemption theme. *See* § 3[b], *"Research Preemption" Confusion in Mayo* (quoting 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 terms of the policy arguments behind the denial of patent-eligibility in the case law from *Bilski* to *Alice* the constant drumbeat is one of "preemption", that grant of a patent to an invention will "preempt" research or use of, for example, the DNA discovered in *Myriad.*

♦ ♦ ♦

§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".

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

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

one judicial descriptor. This discussion is meant to guide examiners and ensure that a claimed concept is not identified as an abstract idea unless it is similar to at least one concept that the courts have identified as an abstract idea.

"When identifying abstract ideas, examiners should keep in mind that judicial exceptions need not be old or long-prevalent, and that even newly discovered judicial exceptions are still exceptions, despite their novelty. For example, the mathematical formula in *Flook*, the laws of nature in *Mayo*, and the isolated DNA in *Myriad* were all novel, but nonetheless were considered by the Supreme Court to be judicial exceptions because they were ''basic tools of scientific and technological work' that lie beyond the domain of patent protection." The Supreme Court's cited rationale for considering even 'just discovered' judicial exceptions as exceptions stems from the concern that 'without this exception, there would be considerable danger that the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon them.'' The Federal Circuit has also applied this principle, for example, when holding the concept of using advertising as an exchange or currency abstract in *Ultramercial*, despite the patentee's arguments that the concept was 'new'."

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

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

"The concept of the *prima facie* case is a procedural tool of patent examination, which allocates the burdens going forward between the examiner and applicant. In particular, the initial burden is on the examiner to explain why a claim or claims are unpatentable clearly and specifically, so that applicant has sufficient notice and is able to effectively respond. For subject matter eligibility, *the examiner's burden is met by clearly articulating the reason(s) why the claimed invention is not*

eligible, for example by providing a reasoned rationale that identifies the judicial exception recited in the claim and why it is considered an exception, and that identifies the additional elements in the claim (if any) and explains why they do not amount to significantly more than the exception. This rationale may rely, where appropriate, on the knowledge generally available to those in the art, on the case law precedent, on applicant's own disclosure, or on evidence."

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

§ 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 iFistssue 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

As seen from the discussion earlier in this chapter, 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 seeming 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. Claiming Patent-Eligible Subject Matter

The present chapter is provided for the basis of drafting a patent application designed to be a test case challenging denials of patent-eligibility under Section 101.

"Inventive" applications of software and biotechnology innovations as well as diagnostic methods have come under special scrutiny under 35 USC § 101 through a series of cases denying patent-eligibility starting with *Bilski* v. *Kappos*, 561 U.S. 593 (2010)(software), and continuing with *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)(diagnostic method); the *Myriad* case, *Ass'n for Molecular Pathology v. Myriad Genetics., Inc.*, 133 S. Ct. 2107, 2116 (2013)(DNA); and *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014)(software). Undoubtedly the most extreme denial of patent-eligibility based upon *dicta* in *Mayo* is *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __(Fed. Cir. 2015)(Reyna, J.).

In view of the case law, how should one claim and provide supporting disclosure for innovative software that is considered "abstract"? For an invention involving a combination of elements including a product of nature? A derivative of a product?

For a *first* patent application drafted "today", it is important to draft a *disclosure* that will support a wide variety of claims that may be the most apt way of defining the invention based upon the evolving standards of patent-eligibility

that will be in force through case law modifications "tomorrow", the time three or so years down the road when the application will be first examined.

The Patent Office *does* provide guidance on patent-eligibility, but following such guidance for drafting a patent application is dangerous. Such guidance is relatively unimportant in drafting a specification "today", because the case law is certainly in a fluid, moving shape that will change over time. In a sense, Patent Office guidance is a negative double whammy: To the extent that an applicant targets his specification and claims today to confirm to Patent Office guidance and that guidance is *too liberal vis a vis* the case law, an opponent can challenge the grant at the Patent Trial and Appeal Board in a Post Grant Review. If the guidance is *too strict* an applicant following this guidance shortchanges his patent position. Therefore, attention is focused in this book on the statute, rules and case law, and not on such Patent Office guidance.

In considering patent-eligibility under 35 USC §101 it must be remembered that the focus of this book is on drafting a *first* filing, "today", the likely priority application for a final application that will be examined "tomorrow", several years from now. Even if this first filing turns out to be the *only* application that will be examined, the first action in the application is likely to take place three or more years down the road: At that time, "tomorrow", the patent-eligibility law will undoubtedly be more moderate than the current state of the law where we may be at the point of the ultimate swing of the patent-eligibility pendulum to the dark side, away from patent-eligibility. Overall, in an historical overview of the law of patent-eligibility since the early seventeenth century Statute of Monopolies, the current mini-era of anti-patent challenges is just five years old, starting with the infamous Supreme Court *Bilski* decision: The pendulum *will* swing back, away

from the extreme result recently reached in *Ariosa*. *See* § 11[a], *Patent-Eligibility Law in a State of Flux.*

Ariosa presents perhaps the best example where a claim *is* (or *should be*) patent-eligible, but falls short by the rigid *dicta* in *Mayo.* The invention in *Ariosa* permits DNA testing of a fetus *without* invasive sampling of amniotic fluid: This is accomplished by drawing a maternal blood sample and *amplifying* its DNA content through polymerase chain reaction so that what would otherwise be a *de minimus* amount of DNA that could not be tested, instead permits DNA testing of the maternal blood for foetal DNA content. It is impossible to consider the invention in *Ariosa* as anything short of pioneer, and most certainly a nonobvious invention or – in the words of the Supreme Court patent-eligibility cases – one that has an "inventive step". Yet, dissecting the claims in *Ariosa* and following *Mayo* has led to a conclusion that the claims lack patent-eligibility under 35 USC § 101. Undoubtedly, if *Ariosa* were to gain *certiorari* the case would represent a strong challenge to the scope of *Mayo.* *Id.*

Given the uncertainties of how the law will evolve in the coming years, how should a specification be drafted today to account for such changes? In the context of drafting a first, priority filing, the challenge for "today" is to draft a first application that will be in a position for favorable examination "tomorrow". As for any invention, it is important to identify an "inventive" feature – what is nonobvious under 35 USC § 103. Then, the disclosure for the application to be filed "today" should include every detail of the environment of that inventive feature. The immediate goal is to provide *support* for whatever claim may be best suited to the patent-eligibility law of "tomorrow", at a time when the application

will be examined and at a time when support will be needed for claims yet to be drafted. *See* § 11[b], *Disclosure "Today" as Basis for Claims "Tomorrow."*

When drafting a claim where an element is either an "abstract" feature or is derived from a "natural" product it is important to provide basis for a combination keyed to an "inventive" feature, whether that is a specific element or subcombination or the invention "as a whole". This will provide basis at a later date for drafting a combination claim that accentuates the inventive feature. *See* § 11[b][1], *Combination Definition Integrating an Inventive Feature*. The inventive feature should be integrated as an essential feature of the combination. *See* § 11[b][2], *Pinpointing the Inventive Feature in a Combination Claim.* Care must be taken to demonstrate the integral nature of a combination invention and to thus focus on the inventiveness – nonobviousness – of the claimed invention *as a whole. See* § 11[b][3], *"Conventional" Element vs. Combination "As a Whole".* As an example of a successful approach consider a "Diehr claim". *See* § 11[b][4], *Diehr vs. a Simplistic "Apply it" Claim Approach.*

§ 11[a] Patent-Eligibility Law in a State of Flux

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 of such fetal DNA are present in the maternal bloodstream permitted use of "polymerase chain reaction ("PCR") [which is] a widely used technique in molecular biology that was invented by Dr. 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 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 (1852) (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).

§11[a][1] Consideration of the Invention "as a Whole"

Stretching the *dicta* in *Mayo* to conclude that the invention in *Ariosa* lacks an "inventive" feature both fails to understand the limited holding of *Mayo* and that a stretched interpretation of *Mayo* runs smack into other lines of Supreme Court case law The *Adams Battery* case is instructive as to the "inventive" or nonobviousness nature of the invention in the *Ariosa* case.

As explained in *KSR:*

In *United States v. Adams*, 383 U.S. 39, 40 (1966), a companion case to *Graham [v. John Deere, 383 U.S. 1 (1966)]*, the Court considered the obviousness of a 'wet battery' that varied from prior designs in two ways: It contained water, rather than the acids conventionally employed in storage batteries; and its electrodes were magnesium and cuprous chloride, rather than zinc and silver chloride. The Court recognized that *when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.* 383 U.S. at 50-51. It nevertheless rejected the Government's claim that Adams' battery was obvious. The Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *Id.*, at 51-52. *** 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."
KSR, __ U.S. at ___ (emphasis supplied).

It is impossible to read the specification of the patent in the *Ariosa* case and come to the conclusion that the invention lacks an "inventive" feature.
As explained in the *Adams Battery* case:

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

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

The majority in *Ariosa* explains that "[i]t is undisputed that the existence of [cell-free fetal DNA] in maternal blood is a natural phenomenon. [The patentees have not] created or altered any of the genetic information encoded in the [cell-free fetal DNA], and it is undisputed that the location of the nucleic acids existed in nature before [the inventors] found them. The method ends with paternally inherited [cell-free fetal DNA], which is also a natural phenomenon. The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring."

But, the starting material in the first step of the process in *Ariosa* was *not* "naturally occurring" but instead was *amplified* DNA. It is uncontested that, as explained by the majority, prior to the invention, maternal plasma and serum from maternal blood samples had previously been discarded as medical waste. The

inventors discovered cell-free fetal DNA [ ] in such maternal plasma and serum in such blood samples previously thought of as mere waste.

It is manifest that the invention was a breakthrough. As pointed out in the separate opinion that distinguished itself from the majority:

"Prior to the [ ] patent, prenatal diagnoses required invasive methods, which 'present[ed] a degree of risk to the mother and to the pregnancy.' The available 'techniques [we]re time-consuming or require[d] expensive equipment.' [An expert] testified that 'despite years of trying by multiple methods, no one was ever able to achieve acceptable success and accuracy.' In [this] groundbreaking invention, [the inventors] 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 … 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 [ ] patent claims a new method that should be patent eligible. *** 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)."

Dissecting the claim into its separate elements the majority "conclude[d] that the practice of the method claims does not result in an inventive concept that transforms the natural phenomenon of [maternal DNA] into a patentable invention." The mistake made by the majority was to put together conventional steps to reconstruct the invention in hindsight when there was clearly no *motivation* to combine these steps.

The majority simply overlooks the fact that there is absolutely no *reason* in the prior art to combine the two steps, but in an obviousness determination it is necessary to provide such a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR Int'l Co. v. Teleflex*, 550 U.S. 398, 418 (2007). The majority overlooks the fact that the invention *as a whole* must be considered to determine whether there is an "inventive step" or – to use the wording of the statute – an *unobvious* difference versus the prior art. The individual steps of the process in *Ariosa* were conventional, as were the steps in the Ochiai and Brouwer processes in *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995), and *In re Brouwer*, 77 F.3d 422 (Fed. Cir. 1996). In each case, each step of the claimed process was completely conventional.

Under the *Ochiai* and *Brouwer* cases it is manifest that there *is* an inventive concept in the invention of the *Ariosa* case that consists of the *combination* of otherwise conventional elements because of the breakthrough discovery to put the pieces of the combination together. The majority fails to give proper weight to the fact that there is absolutely no teaching in the prior art of step (a), the *amplification* of the DNA. There was clearly no *motivation* for a worker skilled in the art to amplify the DNA as nobody in the prior art appreciated that the otherwise insignificant of DNA in maternal fluid could be used for DNA testing. Thus, while it is obvious *how* to amplify DNA there was no *reason* to do so, absent the discovery by the patentees. Putting the puzzle pieces of the several elements together is only possible in hindsight without the inventive contribution made by the inventors as to how to put the puzzle together.

The failure to view the invention *as a whole* and the absence of *motivation* to combine otherwise conventional steps is explained in detail in the *Ochiai* case. The Board in *Ochiai* denied patentability because each of the steps of the claimed invention were conventional: "The [prior art] references *** abundantly demonstrate the routineness of the claimed process. Thus, the Court rejected the argument that a conventional manipulation or reaction was unobvious "notwithstanding the specific starting material or resulting product or both, is not to be found in the prior art". *Ochiai,* 71 F.3d at 1568 (quoting the Board's affirmance). The Board reasoned that:

"We are not here concerned with the patentability of the starting materials, the final compounds or other processes of making the [cephem] compounds. We are concerned only with the claimed process and the patentability thereof. Cases such as *In re Larsen*, 292 F.2d 531 (CCPA 1961); *In re Albertson*, 332 F.2d 379 (CCPA 1964) and, particularly, *In re Durden*, [763 F.2d 1406 (Fed. Cir. 1985)], all of which were directed to processes of making chemical compounds, are controlling herein.... In each case, a material A, either known or novel, was subjected to a standard process of reacting with a standard reactant, B, in order to produce the result expected from the reaction of A with B. Indeed in Albertson as in the instant case, the only manipulative step of the process is that which is embodied in the word 'reacting.'"

Id. In reversing the Board, the court in *Ochiai* stated that:

"One having no knowledge of this acid could hardly find it obvious to make any cephem using this acid as an acylating agent, much less the particular cephem recited in claim 6. In other words, it would not have been obvious to those of ordinary skill in the art to choose the particular acid of claim 6 as an acylating agent for the known amine for the simple reason that the particular acid was unknown but for Ochiai's disclosure in the '429 application. As one of our predecessor courts had occasion to observe, in a case involving a highly analogous set of facts, 'one cannot choose from the unknown.'"

Ochiai, 71 F.3d at 1569-70 (quoting *In re Mancy*, 499 F.2d 1289, 1293 (CCPA 1974))(footnote omitted). The Board added its further analysis; as explained by the court:

"The Board noted that Ochiai's specifically claimed acid is 'similar' to the acids used in the prior art. Likewise, the examiner asserted that the claimed acid was 'slightly different' from those taught in the cited references. Neither characterization, however, can establish the obviousness of the use of a starting material that is new and nonobvious, both in general and in the claimed process. The mere chemical possibility that one of those prior art acids could be modified such that its use would lead to the particular cephem recited in [the claim] does not make the process recited in [the claim] obvious "unless the prior art suggested the desirability of [such a] modification." *In re Gordon*, 733 F.2d 900, 902 (Fed.Cir.1984). As we noted above, the examiner discussed no references containing any suggestion or motivation either (a) to modify known acids to obtain the particular one recited in [the claim], or (b) to obtain the particular new and nonobvious cephem produced by the process of [the claim 6. In short, the prior art contains nothing at all to support the conclusion that the particular process recited in [the claim] is obvious."

Ochiai, 71 F.3d at 1570. *Ochiai* was followed in a similar situation in *Brouwer*:

"The test of obviousness vel non is statutory. It requires that one compare the claim's 'subject matter as a whole' with the prior art 'to which said subject matter pertains.' 35 U.S.C. § 103. The inquiry is thus highly fact-specific by design. This is so 'whether the invention be a process for making or a process of using, or some other process.' *In re Kuehl*, 475 F.2d 658, 665 (CCPA 1973). When the references … fail to establish a prima facie case of obviousness, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071 1074 (Fed.Cir.1988).

"Applying this statutory test to the art of record, we conclude that Brouwer's process invention was not prima facie obvious. Although the prior art references … teach a generic chemical reaction of a compound containing an active methylene group with an ester of vinylsulfonic acid, we have made clear that '[t]he mere fact that a device or process utilizes a known scientific principle does not alone make that device or process obvious.' *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044 1053 (Fed.Cir.1988). See also *Lindemann*

Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452 1462 (Fed.Cir.1984) (same). * * * Without first knowing Brouwer's claimed process steps or the composition resulting from those steps, there is simply no suggestion in the references cited by the examiner to practice the claimed process. It was therefore not prima facie obvious."

In re Brouwer, 77 F.3d at 425.

§ 11[a][2] Focus on what is Claimed

In claim 1 of the invention in the *Ariosa* case the patentee utilizes fluid from the mother of a fetus where DNA has been *amplified*, absent which the minute traces of fetal DNA in the mother could not be detected. There was no recognition in the prior art that there was fetal DNA in the mother's fluid that could be basis for genetic testing.

The invention in *Ariosa* thus deals with a method to determine whether a particular DNA *exists* in a blood sample where there was no reason that a worker skilled in the art would think that such DNA would or could be present in the blood sample.

The invention in the *Ariosa* case has nothing to do with creating a derivative of a natural product based upon that natural product, but rather is simply a method to test whether the natural product, itself, is *present* in a particular sample where there was no reason to believe that such DNA could be present in the sample. The *Ariosa* case thus has nothing to do, for example, with the creation of a product derived from nature, but rather provides a test to see whether a natural product is present in a sample where there was no reason to believe it could exist. The case thus has nothing to do with the principles of the *Myriad* case, *Ass'n for Molecular*

Pathology v. Myriad Genetics., Inc., 133 S. Ct. 2107 (2013); nor *Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 132 S. Ct. 1289 (2012).

The invention in *Ariosa* thus not involve the situation of recognizing the natural properties of DNA, but instead involved the situation where a worker skilled in the art did not know the *existence* of a particular DNA in a fluid sample. There was thus no *motivation* for a worker skilled in the art to substitute amplified DNA in the process of the *Ariosa* litigation.

"Motivation" to lead a worker skilled in the art to combine several elements together must be present to establish obviousness, whether that motivation is implicit or explicit. *"*One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a *known problem* for which there was an obvious solution encompassed by the patent's claims.") *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419-20 (2007)(emphasis added).

There was no "known problem" to provide where motivation to amplify the DNA for inclusion in the patented process. *Recognition* of a problem is one way to establish motivation, as explained in *Cross Medical Products, Inc. v. Medtronic Sofamor Danek*, 424 F.3d 1293 (Fed. Cir., 2005)(Linn, J.). Thus:

Evidence of a motivation to combine references need not be in the form of prior art. *See* [*Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1338-39 (Fed.Cir.2004)]. Evidence that a person of ordinary skill in the art recognized the same problem to be solved as the inventor and suggested a solution is, at the least, probative of a person of ordinary skill in the art's willingness to search the prior art in the same field for a suggestion on how to solve that problem. See *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed.Cir.1996) (Motivation to combine "may also come from the nature of a problem to be solved, leading inventors to look to references relating to possible solutions to that problem." (citing *In re Rinehart*, 531 F.2d 1048, 1054 (CCPA1976))); *In re*

Huang, 100 F.3d 135, 139 n. 5 (Fed.Cir.1996) (stating that problem well-known to a person of ordinary skill in the art would have directed that person of ordinary skill to the reference teaching the missing elements); see also, e.g., *In re Gartside*, 203 F.3d 1305, 1320-21 (Fed.Cir.2000) (recognizing that motivation to combine can come from the nature of the problem to be solved*); In re Rouffet*, 149 F.3d 1350, 1355 (Fed.Cir.1998) (same).

Cross Medical Products, 424 F.3d at 1323. The *Kaslow* case has a similar discussion: "[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." *In re Kaslow*, 707 F.2d 1366, 1373 (Fed. Cir. 1983)(quoting *In re Sponnoble*, 405 F.2d 578, 585 (CCPA 1969); *see also In re Zurko*, 111 F.3d 887, 890 (Fed. Cir. 1997), *rev'd on other grounds*, 527 U.S. 150 (1999)(quoting *Sponnoble*, 405 F.2d at 578).

§ 11[a][3] *Ariosa* is Keyed to Extreme *Dicta* from *Mayo*

Both Professor Jeffrey Lefstin and Dr. Kevin Noonan have criticized the *Ariosa* majority opinion.

That the result in *Ariosa* was not compelled by the *holding* in *Mayo* is explained in detail by the noted scholar, Professor Lefstin:

"In *Ariosa*, the Federal Circuit has endorsed a highly restrictive interpretation of the test for patent-eligibility, one that was not mandated by *Mayo* itself. A test for 'inventive' application was only one of several possible analytical approaches set forth in *Mayo*. *Mayo* also suggested a test of non-generic application for patent-eligibility: that a claim must do more than state a law of nature or abstract idea, and append an instruction to 'apply it.' That was the aspect of *Mayo* stressed by *Alice*, which emphasized generic application far more than inventive application.

"As I argued in a recent paper, [Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence of Abstractions*, 16 North Carolina Journal of Law and Technology 647 (2015),] under a test of generic application, the claims in *Ariosa* might fare differently than the claims in *Mayo*. The claims in *Mayo* represented generic applications, because they did no more than reveal the results of the underlying relationship between 6-thioguanine levels and therapeutic efficacy. Arguably, at least some of the *Ariosa* claims do more than that: rather than claiming the natural phenomenon ([cell-free fetal DNA] in the maternal circulation) itself, they employ the natural phenomenon as a means to a achieve a different end (diagnosing a genetic condition of the fetus)."

"Moreover, the *Ariosa* opinion appears to endorse dissection of the claim to a degree not only contrary to *Diehr*, but beyond that suggested by *Flook* itself. While *Flook* explained that "the process itself" must be new and useful, *Ariosa* suggests that the individual steps of the process must be new and useful, and identifies the discovery of [cell-free fetal DNA] as "[t]he only subject matter new and useful as of the date of the application." Given that most inventions consist of rearrangements of old elements, it is difficult to understand how the court can refrain from addressing the claim steps as an ordered whole, as mandated by *Mayo* itself.

"And that highlights what is perhaps the most puzzling (or disturbing) aspect of *Ariosa*. According to Judge Linn's concurrence, the steps of the method *were* new: at the time of the invention, no one was amplifying paternally-inherited sequences from maternal serum or plasma, because no one thought that those fractions contained significant amounts of fetal DNA. That contrasts with *Mayo*, where the acts recited in the method were identical to those performed in the prior art. Yet Judge Linn believed that the Supreme Court's "blanket dismissal of conventional post-solution steps" in *Mayo* left no room to distinguish the *Ariosa* claims on those grounds.

"If the step of amplifying paternally inherited DNA from serum or plasma was new, by what analysis could the court could regard it as 'well-understood, routine, and conventional activity'? One way would be to sub-dissect that step into the conventional step of obtaining a cell-free fraction, and the conventional step of amplifying a sample containing DNA. That approach seems to lead to the *reductio ad absurdum* that most biotechnology processes are patent-ineligible, because they consist of the conventional steps of transferring drops of fluid from one tube to another.

"The alternative way would be to ask if the step of amplifying paternally inherited DNA would be obvious once it was known that there was [cell-free fetal DNA] in the maternal bloodstream. In other works, assume the patentee's discovery to be already known, and ask if the invention is obvious once the discovery is assumed away. If that is truly the interpretation of *Mayo* signaled by *Ariosa*, then the case promises to cast a long shadow on the patent-eligibility of inventions based on discovery in the future."

Jeffrey A. Lefstin, *Ariosa v. Sequenom and the Path Ahead for Subject-Matter Eligibility*, Patently O Blog (June 14, 2015).

Even before the decision was reached in *Ariosa,* Professor Dennis Crouch foresaw the problems that the panel faced. *See* Professor Dennis Crouch, *Sequenom v. Ariosa: Invalidating the patent on Non-Invasive Pre-Natal Genetic Testing*, Patently O Blog (September 9, 2014)(discussing the then-pending appeal at the Federal Circuit). Following the decision, Dr. Kevin Noonan provided a sharply focused critique of the majority view in *Ariosa:*

[T]he Court appreciated that the inventors had found cell-free fetal DNA [ ] in maternal plasma or serum "*that other researchers had previously discarded as medical waste*" (*emphasis added [by Dr. Noonan]*). Foreshadowing their reasoning, the panel then state that "[a]pplying a combination of known laboratory techniques to their discovery, Drs. Lo and Wainscoat implemented a method for detecting the small fraction of paternally inherited [cell-free fetal DNA] in maternal plasma or serum to determine fetal characteristics, such as gender" (by which the opinion avoids the more significant uses such as detecting Downs syndrome and other fetal genetic defects). And more foreshadowing occurs when they characterize the development of this test as being a "discovery."

The opinion then acknowledges through the parties that the claims are not directed to [cell-free fetal DNA] *per se* or paternally inherited species thereof. In language that parallels Justice Thomas's language in Section III of his *Myriad* opinion, the opinion states that the '540 patent claims methods of using [cell-free fetal DNA]

and then sets forth the panel's understanding of the technical basis for the claimed methods and the procedural particulars of the case below.

The panel's analysis is best understood using the Court's own language, to better appreciate the basis for this decision:

"In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), the Supreme Court 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 a patent-ineligible concept. *Id.* at 1297. If the answer is yes, then we next consider the elements of each claim both individually and 'as an ordered combination' to determine whether additional elements "transform the nature of the claim" into a patent-eligible application. *Id.* at 1298. The Supreme Court has described the second step 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 1294; *see also Digitech Image Techs., LLC v. Elecs. For Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014) ('Without additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible.').

Applying this understanding of the Supreme Court's teachings regarding diagnostic claims, the opinion states:

"It is undisputed that the existence of [cell-free fetal DNA] in maternal blood is a natural phenomenon. [The patentee] does not contend that [the inventors] Drs. Lo and Wainscoat created or altered any of the genetic information encoded in the [cell-free fetal DNA], and it is undisputed that the location of the nucleic acids existed in nature before Drs. Lo and Wainscoat found them. The method ends with paternally inherited [cell-free fetal DNA], which is also a natural phenomenon. The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring."

Of course, what the claimed methods end with are *amplified* [cell-free fetal DNA] *and* the diagnostic information that is discerned (but not claimed) using the method.

The opinion then takes isolated statements from the specification to support this conclusion (again, stating that [cell-free fetal DNA] was "routinely" discarded) and

that the inventors surprisingly found that detecting [cell-free fetal DNA] could be used to render clinical diagnoses of fetal abnormalities non-invasively.

Of course, it is but a short analytical leap to find that the detection methods were simply "routine, conventional and well-understood" because the panel does not consider the claim as a whole but has broken its analysis into pieces (contrary to Supreme Court's *Diamond v. Diehr* decision). Accordingly, the panel determines that there is no "inventive concept" in the claims (bizarrely, relying as did the District Court on *Parker v. Flook*). (The applicability of that decision on life science inventions should have been firmly put to bed in Judge Rich's *In re Bergy* decision.) The next portion of the opinion nicely sets out the logical and legal flaws in the panel's decision:

"Like the patentee in *Mayo*, [the patentee here] contends that the claimed methods are patent eligible applications of a natural phenomenon, specifically a method for detecting paternally inherited [cell-free fetal DNA]. Using methods like PCR to amplify and detect [cell-free fetal DNA] was well-understood, routine, and conventional activity in 1997. The method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect [cell-free fetal DNA]. Because the method steps were well-understood, conventional and routine, the method of detecting paternally inherited [cell-free fetal DNA] is not new and useful. The only subject matter new and useful as of the date of the application was the discovery of the presence of [cell-free fetal DNA] in maternal plasma or serum."

Unlike the patentee in *Mayo*, the inventors of the claimed invention here did something not done before their invention (detecting [cell-free fetal DNA] in maternal blood). In contrast, *every* step in the methods claimed in *Mayo* had been performed in the prior art; the only inventive aspect in those claims was the therapeutic ratio, which the Court found to be a 'natural law.' Accordingly, the *Mayo* claims did nothing more than recite the natural law. That is not the case here. Tragically, the remainder of this portion of the opinion recites the tedious evidence from the specification regarding known amplification and detection methods while ignoring that these methods had never been used to detect [cell-free fetal DNA] in maternal blood."

The opinion then visits preemption (sadly, the Circuit Court responsible for interpreting patent law does not correctly state the standard, *i.e.*, *undue* preemption; after all, *all* claims are preemptive in nature). Fortunately, the panel does not follow the District Court through the looking glass of requiring for patent

eligibility that every newly claimed method to recite not only a new method but that there be commercially viable, non-infringing alternatives available at the time an application is filed. Instead, the Court considers the preemption question moot once claims have been determined to be patent ineligible.

Finally, the Court insulates itself from the negative consequences its decision has on innovation by citing language (dicta) in *Myriad* that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry," illustrated by the interpretation that "[t]he discovery of the BRCA1 and BRCA2 genes was a significant contribution to the medical field, but it was not patentable" (ignoring the fact acknowledged twelve pages prior in the opinion that the inventors were *not* claiming [cell-free fetal DNA]).

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Judge Linn [in his concurrence] hoists the panel's decision on the petard of superior Supreme Court precedent:

"In short, [the patentee]'s invention is nothing like the invention at issue in *Mayo*. [Patentee] "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 (1852) (same); *see generally* Jeffrey A. Lefstin, *Inventive Application: a History*, [67 Fla. L. Rev. 565 (2015)] (analyzing traditional notions of patent eligibility of newly discovered laws of nature)."

* * *

It is clear that the Federal Circuit (or at least the members of this panel) believe that they are operating under a mandate from the Supreme Court regarding patent eligibility. On the contrary, the Court itself has on many occasions made it clear that they view their role (in patent law and otherwise) as setting forth the broad contours of the law that they expect the inferior courts to use to develop the law properly. In view of the lack of clarity in the *Mayo* opinion, a third year law student could distinguish this case from that one in arriving at the correct conclusion of patent eligibility. Nothing more than Supreme Court precedent itself (specifically, the *Diamond v. Diehr* decision which the Court did not overturn in *Mayo*) is needed for the task. The issue is not a lack of analytical and doctrinal tools but the will to employ them, which these members of the Federal Circuit do not seem to have had in rendering this decision. But shielding the Court from the

consequences of their bad decisions does them a disservice. If the Court intended to exclude from patent eligibility *all* genetic (nay all *types* of) diagnostic methods, the Federal Circuit owes it to the Court to give them the opportunity to say so clearly and reap the political consequences. * * *

Kevin E. Noonan, *Ariosa Diagnostics, Inc. v. Sequenom, Inc. (Fed. Cir. 2015)*, Patent Docs blog (June 22, 2015).

§ 11[a][4] The *Ariosa* Invention does not "Preempt" Research

The invention in *Ariosa* had absolutely nothing to do with the discovery of a product of nature. *Ariosa* thus has nothing to do with "preemption" of the DNA involved in the *Ariosa* claimed invention. Rather, the invention in *Ariosa* involved a new method to *identify* the presence of certain DNA. By analogy, consider the situation where a natural product cannot be identified by the human eye, without more, but *can* be identified through use of a "microscope". Imagine further that an inventor has discovered a new "microscope" that makes it easier and more accurate to identify the particular natural product. It is perfectly logical that one could claim either that "microscope" or a method of testing for the presence of the natural product by use of that "microscope", and that – assuming nonobviousness of the "microscope" – one should obtain a patent on the "microscope" or the method of use of the "microscope" to identify the natural product.

This is in essence the situation of the *Ariosa* case where the invention involves a new method for detecting the presence of DNA in a fluid sample but makes no claim to the DNA itself: There is no "preemption". Thus, a cornerstone argument in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289

(2012), against patent-eligibility of inventions involving "natural" subject matter is that granting patents on a derivative or use of the "natural" subject matter "preempts" research on a phenomenon of nature. Thus, it is stated that "[*Benson*] warn[s] us against upholding patents that claim processes that *too broadly preempt* the use of a natural law." *Mayo*, 132 S.Ct. at 1294 (citing *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972)). An argument that the *dicta* in *Mayo* leads to the conclusion that the invention in *Ariosa* "preempts" research demonstrates the breadth of the *dicta* and leads to a result that has absolutely no impact whatsoever on the preemption of research on or use of the natural principle of the invention in *Ariosa*: The invention in *Ariosa* is a method to test for the existence of DNA in a blood sample and has nothing to do with patenting or using that DNA or a derivative of that DNA. There is simply no preemption even for commercial use of that DNA.

§ 11[a][5] Patents Do Not "Preempt" Research

Even if the use of the natural DNA in the *Ariosa* case were within the scope of claims of the patent in that case, this leaves the more fundamental question: Can the use of an invention to *experiment on* that invention *ever* be an act of infringement to see, for example, how the invention operates or to compare it to the prior art or to otherwise conduct research on the invention to make further improvements or design around the invention?

Until the Federal Circuit came into existence the answer was a clear "no". Wegner, *Post*-Merck *Experimental Use and the "Safe Harbor,"* 15 Fed. Cir. B.J. 1 (2005)(herein: "Post-Merck Paper").

The Federal Circuit must accept a share of the responsibility for the failure of the patent community to understand the fundamental right to experiment "on" a patented invention. Despite a deep split within the Federal Circuit on this issue the appellate court has never seen fit to consider the issue *en banc.*

The starting point to understand the Federal Circuit split viewpoint is the state of the law leading up to *Merck KGaA v. Integra Lifesciences I, Ltd.,* 545 U.S. 193 (2005), as reported in the Post-Merck Paper. The dominant view of the former, recently retired Chief Judge is seen from *Integra Lifesciences I, Ltd. v. Merck KgaA*, 331 F.3d 860 (Fed. Cir. 2003)(Rader, J.) *rev'd*, *Merck KGaA v. Integra Lifesciences I, Ltd*., 545 U.S. 193 (2005). The case involved a classic fact pattern of an experimentation "on" a patented invention. Yet, the dominance at the time of the view of the former Chief Judge was manifested by the accused infringer *refraining* from even raising this issue before the Federal Circuit. As explained in the majority opinion by the former Chief Judge, "Judge Newman's dissent [in this case does not] note that the judge-made [experimental use] doctrine is rooted in the notions of de minimis infringement better addressed by limited damages." *Integra Lifesciences I,* 331 F.3d at 863 n.2.

One panel leading up to the *Mayo* case uncritically accepted the view that "the[ ] exceptions [to statutory patent-eligibility under 35 USC § 101] have defined the reach of the statute as a matter of statutory *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.) at 174-75), *subsequent proceedings sub nom Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 132 S. Ct. 1289 (2012). The holding in *Le Roy*

v. Tatham had absolutely nothing to do with patent-eligibility but rather dealt with the claiming of technology involving a lead pipe! A lead pipe!

While there have been recent opinions where some panels seem to understand that there *is* a right to experiment "on" a patented invention, the other side of the coin is that some panels continue to take the *Deuterium* route. *See, e.g., Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, 718 F.3d 1350, 1356 (Fed. Cir., 2013)(Dyk, J.)(quoting *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1352–53 (Fed.Cir.2000) (Rader, J., concurring) ("[T]his court has not tolerated the notion that a little infringement—de minimis infringement—is acceptable infringement or not infringement at all.").

§ 11[a][6] Historical Case Law and Patent "Preemption"

Preemption became important with the *Bilski* case, *Bilski v. Kappos*, 561 U. S. 593 (2010):

"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*."

No one, we suppose will maintain that Fulton could have taken out a patent for his invention of propelling vessels by steam, describing the process and machinery he used, and claimed under it the exclusive right to use the motive power of steam, however developed, for the purpose of propelling vessels. It can hardly be supposed that under such a patent he could have prevented the use of the inproved machinery which science has since introduced; although the motive power is steam, and the result is the propulsion of vessels. Neither could the man who first discovered that steam might, by a proper arrangement of machinery, be used as a motive power to grind corn or spin cotton, claim the right to the exclusive use of steam as a motive power for the purpose of producing such effects.

§ 1516[a][7] Importance of Simple, Well Defined Claims

An Examiner's work load is greatly reduced where the claims are cleanly drafted, few in number and where claim elements at the point of novelty are clearly defined in the *Summary of the Invention.*

Poorly Defined Claims May Defeat the Possibility of a Complete First Action on the Merits

It is very important that any *definitions* of claim terminology appear in a *Summary of the Invention* so that the Examiner will quickly find the definitions and not waste time trying to figure out the scope of claim terminology from the *Detailed Description of the Invention.* To the extent that it takes a considerable amount of time for an Examiner to figure out the true scope of claims, this time – *together with other factors* may require more time for a complete action on the merits than the Examiner has allocated for the first action:

A patent examiner has only so much time to conduct a first Office Action on the merits which includes a review of all the claims to see that they are formally correct in compliance with 35 USC § 112, a prior art search; evaluation of the patentability of the claimed invention over the prior art; and preparing a first Office Action. If the Examiner allocates, say, six hours for all of these tasks, and the applicant presents a holistically prepared application that can be examined in, say, three hours, then it is to be expected that the Examiner *will* do a complete and thorough first Office Action. If, however, the cumulative effect could well *exceed* the allocated time if there is a presentation of large numbers of claims, formal errors in the claims, the citation of, say, forty references. *Then*, it is more than likely that the Examiner will focus on finding a collection of the best prior art and make a rejection of all the claims over a mosaic combination of references. Above all, the case should be in a form *simple to examine.*

§ 11[b] Disclosure "Today" as Basis for Claims "Tomorrow"

Generic claim 1 in any application should, as a general rule, recite the "minimum elements" necessary to establish nonobviousness of an invention. In the case of a claim on the borderline of Supreme Court patent-eligibility standards, it is important to include at least one physical limitation as a prominent feature of the claims, and to include as many physical elements as possible *which are necessary for the commercial application of the invention.*

Perhaps more importantly, a "Diehr claim" should be presented that is modeled after the claims in *Diehr* which are cast as a method for curing rubber. This is in contrast to the "apply it" claims which downplay the physical element and have earned the scorn of the Supreme Court

The simple claim that recites an algorithm and essentially nothing more than a general instruction to "apply [the algorithm]" ("apply it") is easy to write but clearly a prescription for denial of patent-eligibility: *Alice Corporation Pty. Ltd. v. CLS Bank International,* 134 S. Ct. 2347, __ (2014), quoting *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1294 (2012)("*Mayo* made clear that transformation [of an abstract idea] into a patent-eligible application requires "more than simply stat[ing] the [abstract idea] while adding the words 'apply it.' ")

Denial of "apply it" claims has been endorsed by the Federal Circuit. "[The court] 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. 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.'"" *Ultramercial, Inc. v. Hulu, LLC*, __ F.3d __, __ (Fed. Cir. 2014)(Lourie, J.)(citations omitted)). As stated by one of the newer members of the court, "*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.'" *Ariosa Diagnostics, Inc. v. Sequenom, Inc*., __ F.3d __, __ (Fed. Cir. 2015)(Reyna, J.)(quoting *Mayo*, 132 S. Ct. at 1294), quoting *Mayo*, 132 S. Ct. at 1294)).

A claim to a combination that includes a "conventional" element is novel and should be nonobvious where there is no reason in the prior art to combine that "conventional" element with the other element (or elements) of a combination claim. This should also be true if the only other element of the claim is itself unpatentable by virtue of being abstract or a product of nature and hence, as such element, lacking patent-eligibility under 35 USC §101 as in *Parker v. Flook*, 437 U.S. 584 (1978).

Under traditional patent principles, there is *novelty* in the combination of elements in each of these situations. In the area where the other component is abstract or a product of nature as in *Flook*, the real question under historic patent law principles is whether the combination is *obvious* under 35 USC § 103.

Flook is foundational case law for more recent Supreme Court decisions relating to 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 *Alice*

Corporation Pty. Ltd. v. CLS Bank International, 134 S. Ct. 2347 (2014). A more balanced view of the role of a "conventional" element is found in *Bilski v. Kappos*, 561 U.S. 593 (2010):

"Flook rejected '[t]he notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process.' *Id*., at 590. The Court concluded that the process at issue there was 'unpatentable under §101, not because it contain[ed] a mathematical algorithm as one component, but because once that algorithm [wa]s assumed to be within the prior art, the application, considered as a whole, contain[ed] no patentable invention.' *Id*., at 594. As the Court later explained, *Flook* stands for the proposition that the prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant postsolution activity.' [*Diamond* v. *Diehr*, 450 U.S. 175, 191-92 (1981)].

"Finally, in *Diehr*, the Court established a limitation on the principles articulated in *Benson* and *Flook*. 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."

To be sure, attempts have been made to minimize the impact of *Diehr* as seen from the *dictum* from Circuit Judge Plager in *Versata Software, Inc. v. SAP America, Inc.*,__ F.3d __, __ (Fed. Cir. 2015)(Plager, J.). In *Versata*, a panel

minimized the precedential importance of *Diamond v. Diehr* on the basis that the claim was couched in terms of an industrial process – a method of curing rubber:

> In *Alice* [*Corporation Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014)], the Court held that claims directed to the abstract idea of intermediated settlement were unpatentable, even though some of the claims required generic computer implementation. In *Bilski* [v. *Kappos*, 561 U.S. 593 (2010)], the Court held that claims directed to the abstract idea of risk hedging were unpatentable. In *Parker v. Flook*, 437 U.S. 584 (1978), the Court held that a mathematical formula for computer alarm limits in a catalytic conversion process was a patent-ineligible abstract idea. In *Gottschalk v. Benson*, 409 U.S. 63 (1972), the Court held that claims involving an algorithm for converting binary-coded decimal numerals into pure binary form were unpatentable since the patent was, in practical effect, a patent on the algorithm itself.
>
> These cases may be contrasted with *Diamond v. Diehr*, 450 U.S. 175 (1981), in which the Court held that a computer-implemented process for curing rubber was patent eligible even though it employed a well-known mathematical equation. It used the equation in a process to solve a technological problem in conventional industry practice."

§ 11[b][1] Combination Definition Integrating an Inventive Feature

A common undercurrent in the patent-eligibility cases particularly since *Bilski* v. *Kappos*, 561 U.S. 593 (2010), has been the concern that a patent on an abstract idea or principle would "preempt" future research. *Alice* is just a more recent iteration of the Supreme Court concern for preemption: "We have described the concern [over § 101] that drives this exclusionary principle as one of pre-emption." *Alice*, 134 S. Ct. at 2354 (quoting *Bilski* v. *Kappos*, 561 U.S. 593, 611-12 (2010)). The concern is the impact of "upholding the patent 'would pre-empt

use of this approach in all fields, and would effectively grant a monopoly over an abstract idea'" *Id.*

Stating that "[l]aws of nature, natural phenomena, and abstract ideas are 'the basic tools of scientific and technological work[,]'" *Alice,* 134 S. Ct. at 2354 (quoting *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013)), the Court notes that "monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it,' thereby thwarting the primary object of the patent laws." *Alice,* 134 S. Ct. at 2354 (quoting *Mayo* and the U.S. Const., Art. I, § 8, cl. 8, that "Congress 'shall have Power . . . To promote the Progress of Science and useful Arts'").

The Court reiterates the position with reference to a mid-nineteenth century case: "We have 'repeatedly emphasized this . . . concern that patent law not inhibit further discovery by improperly tying up the future use of' these building blocks of human ingenuity.'" *Alice,* 134 S. Ct. at 2354 (quoting *Mayo*, citing *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 113 (1854)).

§ 11[b][2] Pinpointing the Inventive Feature in a Combination Claim

In *Alice* the Court also recognizes that it must draw the line to *permit* patenting of inventions because a naked "preemption" argument would foreclose patentability in many areas of technology. Thus, after stating its preemption theory to block patenting of abstract ideas, the Court adds an important caveat:

"At the same time, we tread carefully in construing this exclusionary principle lest

it swallow all of patent law. *Mayo*, [supra]. At some level, 'all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.' Id., …). 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*, [supra], thereby 'transform[ing]' them into a patent-eligible invention, *id.*,…. The former 'would risk disproportionately tying up the use of the underlying' ideas, *id.*,…., 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, 134 S. Ct. at 2354-55.

Nothing in *Alice* in any way suggests that subject matter should be preempted that is both novel and nonobvious, i.e., "inventive". Indeed, the same concerns that motivated the Supreme Court to judicially legislate a standard of "invention" are identically applicable to the concerns expressed by the Supreme Court under the theory of "preemption" in *Alice* and the other patent-eligibility cases.

Instead of dealing with an issue of patent-eligibility, the Court in *KSR* invalidated the "gas pedal" patent on the basis that "Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. 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." *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 427 (2007)(citing U.S. Const., Art. I, § 8, cl. 8). Thus, "[t]hese premises led to the bar on patents claiming obvious subject matter established in *Hotchkiss* [v. *Greenwood*, 52 U.S. (11 How.) 248 (1851),] and codified in § 103." *Id.*

The same theme was stated in *Anderson's-Black Rock: "*Congress may not authorize the issuance of patents whose effects are to *remove existent knowledge from the public domain, or to restrict free access to materials already available." Anderson's-Black Rock, Inc. v. Pavement Salvage Co*., 396 U.S. 57, 61 (1969)(emphasis added).

While the Court in *Alice* seeks to draw a line between what is and what is not patent-eligible based upon preemption, the way the line is drawn is based upon whether the claimed subject matter is "inventive". But, this is synonymous with whether subject matter is non-obvious. The identical preemption concerns apply for both the "abstract" ideas and the clearly conventional technology of the section 103 cases: In both settings, the patent should not preempt known or obvious basic building blocks for future innovation.

If the Supreme Court can be faulted for perpetuating the false idea that patents *preempt* research, the blame must also be shared by the Federal Circuit that has long had an element that shared this viewpoint. A central point of the *Myriad* petition is the notion that any patent *preempts* follow-on research, a problematic premise in the context of two centuries of contrary domestic precedent that has been a model for the major patent regimes around the world.

§ 11[b][3] "Conventional" Element vs. Combination "As a Whole"

One may agree, *arguendo,* that the methodology in *Flook* was wrong and in violation of the "all elements" rule. But, at first blush, the question may be asked: Why does it matter that a "conventional" element of the claim is disregarded in the evaluation of a combination claim?

The principal reason *why* a claim is drafted with plural elements is precisely because it is the *combination* that is evaluated, *as a whole,* in determination of patentability. Thus, if there are elements "A" and "B" in a patented combination and "A", standing alone, is patentable, while "B", standing alone, is conventional, the manifest approach to obtaining maximum breadth would be *not* to claim the combination A+B but claim the element A-alone, because the claim to the element A-alone covers that element, by itself, as well as *any* combination with any manner of other element(s). The only reason *why* the "conventional" element "B" is included in "claim 1" is because element "A" may not be *per se* patentable, but the *combination* may be unexpected (and hence patentable).

The error in *Flook* may be seen from the explanation in *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc*., 807 F.2d 955 (Fed. Cir. 1986)(E. Smith, J.):

> "The dispositive question is not whether the claimed device is an 'invention'; rather, it is whether the invention satisfies the standards of patentability. 35 U.S.C. §§ 100-103. To suggest that [the patentee]'s new combination 'is not necessarily an invention' or otherwise to require some concept of 'inventiveness' or 'flash of genius' for patentability would improperly misplace the focus of 35 U.S.C. Sec. 103.
>
> "That each element in a claimed invention is old or unpatentable does not determine the nonobviousness of the claimed invention as a whole. 'There is no

basis in the law * * * for treating combinations of old elements differently in determining patentability.' As stated in *Stratoflex*:

"The reference to a 'combination patent' is equally without support in the statute. There is no warrant for judicial classification of patents, whether into 'combination' patents and some other unnamed and undefined class or otherwise. Nor is there warrant for differing treatment or consideration of patents based on a judicially devised label. Reference to 'combination' patents is, moreover, meaningless. Virtually all patents are 'combination patents,' if by that label one intends to describe patents having claims to inventions formed of a combination of elements. It is difficult to visualize, at least in the mechanical-structural arts, a 'non-combination' invention, i.e., an invention consisting of a single element. * * *" [*Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540 (Fed.Cir.1983)(original emphasis).]

"Casting an invention as 'a combination of old elements' leads improperly to an analysis of the claimed invention by the parts, not by the whole. That is what seems to have happened here. The critical inquiry is whether ' 'there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.' [*Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed.Cir.1985) (emphasis in original), quoting *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co*., 730 F.2d 1452, 1462 (Fed. Cir. 1984).]"

Custom Accessories, 807 F.2d at 959 (footnotes integrated into text in brackets or deleted).

§ 11[b][4] *Diehr* vs. a Simplistic "Apply it" Claim Approach

The simple claim that recites an algorithm and essentially nothing more than a general instruction to "apply [the algorithm]" ("apply it") is easy to write but clearly a prescription for denial of patent-eligibility: "*Mayo* made clear that transformation [of an abstract idea] into a patent-eligible application requires "more than simply stat[ing] the [abstract idea] while adding the words 'apply it.' " *Alice Corporation Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347, __

(2014)(quoting *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1294 (2012)).

The Federal Circuit has underscored its view that an "apply it" application of an algorithm lacks patent-eligibility: "[The court] 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*, 132 S. Ct. at 1294, 1298). 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)." *Ultramercial, Inc. v. Hulu, LLC*, __ F.3d __, __ (Fed. Cir. 2014)(Lourie, J.); *Ariosa Diagnostics, Inc. v. Sequenom, Inc*., __ F.3d __, __ (Fed. Cir. 2015)(Reyna, J.)(quoting *Mayo*, 132 S. Ct. at 1294)("*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.' "). *See also* § 16[a][7], *Adams and Ochiai Consideration of the Invention "as a Whole"* (discussing the *Adams Battery* case, *United States v. Adams*, 383 U.S. 39 (1966), and *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995)).

The better approach is to provide a claim to an overall process where the algorithm is just one of the elements of the claim as exemplified by the claim in *Diamond v. Diehr*, 450 U.S. 175 (1981), to a method of curing rubber.

§ 11[c] Mythology of *"[S]tare decisis going back 150 years"*

"Although not compelled by the statutory text, the Court has held that "the[ ] exceptions [to statutory patent-eligibility] have defined the reach of the statute as a matter of statutory *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.) at 174-75), *subsequent proceedings sub nom Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 132 S. Ct. 1289 (2012).

To be sure, the Supreme Court itself has characterized the case in similar terms. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)(citing *Le Roy* v. *Tatham*, 55 U.S. (14 How.) 156, 175 (1853))(" "[P]atents cannot issue for the discovery of the phenomena of nature."); *Alice Corp. v. CLS Bank International*, 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.' ")

Beyond *Prometheus*, other Federal Circuit cases discussing *Le Roy v. Tatham* include *In re Bilski*, 545 F.3d 943, 952 (Fed. Cir. 2008)(Michel, C.J.)(quoting *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852)("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."); *Classen Immunotherapies Inc. v. Idec*, 659 F.3d 1057, 1080 (Fed. Cir. 2011)(Moore, J., dissenting) (quoting *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 173 (1853) ("A patent is not good for an effect, or the result of a certain process, as that would

prohibit all other persons from making the same thing by any means whatsoever. This, by creating monopolies, would discourage arts and manufactures, against the avowed policy of the patent laws.").

§ 11[c][1] *Household Coal* Nineteenth Century English Precedent

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 (1852). *See* Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. 565, 594-96 (2015)(analyzing traditional notions of patent eligibility of newly discovered laws of nature); cf. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __, __ (Fed. Cir. 2015)(Linn, J., concurring)("Sequenom's invention is nothing like the invention at issue in *Mayo* [*Collaborative Services v. Prometheus Laboratories, Inc*., 132 S. Ct. 1289 (2012)]. Sequenom 'effectuate[d] a practical result and benefit not previously attained,' so its patent would traditionally have been valid. *Le Roy v. Tatham*, 63 U.S. 132, 135-36 (1859)(quoting *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 (1852) (same); see generally Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. [565, 594-96 (2015)](analyzing traditional notions of patent eligibility of newly discovered laws of nature). But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.").

Le Roy v. Tatham, 55 U.S. (14 How.) 156 (1852), 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). *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 174-5.")

Household Coal, however, had absolutely nothing to do with patent-eligibility, as explained by Professor Lefstin, *supra*.

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

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!

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.

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

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

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

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

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

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

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

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

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:

Particularly in earlier centuries and millennia but still well into the twentieth century, where there is no scientific explanation for a phenomenon, the explanation was often that this was a "nature's secret". As the frontiers of science rolled back the areas of uncertainties, what had been "nature's secret" was now attributable to a rational scientific explanation. One of the last bastions of a mystical belief in "nature's secrets" relates to the explanation of mechanisms of pharmaceutical and agricultural phenomena where there is no explanation available from science.

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

♦ ♦ ♦

APPENDIX: A SEQUENOM WHITE PAPER

I. OVERVIEW

On or shortly before the April 1, 2016, deadline, a petition for *certiorari* will be filed in *Sequenom, Inc. v. Ariosa Diagnostics, Inc*., Supreme Court No. 15A871. A great deal of controversy exists whether the *Sequenom* case represents merely an important case for the patentee, or whether the patent community at large has a stake in the positive evolution of case law that may be possible if *Sequenom* proceeds to the merits stage.

This paper addresses the question whether potential *amici* should "wait and see" at the *certiorari* stage without *amici* participation, and then participate at the merits stage *if* the Court grants *certiorari* – or plunge in as *amici* at the earlier stage.

The *Sequenom* patent, itself, presents an overwhelming case of an invention that is clearly patent-eligible. Whether prospective *amici* should join the Supreme Court case to a great extent depends upon how the *Questions Presented* are styled

in the petition for *certiorari.* Will the *Questions Presented* be styled to highlight manifest patent-eligibility even under the most extreme interpretation of recent case law? If yes, then by all means *certiorari* support should be of positive value.

For example, consider the following *Questions Presented* that would make out a best case scenario:

"It is unquestioned that the invention *as a whole* involving the combination of drawing maternal blood and *amplifiying* the DNA, e.g., with PCR technology, represents a breakthrough and *a fortiori* 'inventive' method.

"It is also unquestioned that the Sequenom invention involves DNA only as the object of *identification* of known DNA, i.e., the invention makes no claim to any DNA of any kind nor to any method of use of DNA.

"The *Questions Presented* are thus:

"(1) Does classic Supreme Court case law requiring consideration of "all elements" of an invention remain viable to determine the patent-eligibility of a method which, *as a whole,* is clearly "inventive." In other words, does the "all elements" rule as applied in *Diehr* trump the dissection of claims as in *Flook*?

"(2) Does case law denying patent-eligibility to claims to DNA, *per se* (or claims to its method of use) preclude patent-eligibility of a claim which merely *identifies* the presence or absence of DNA, but in no way, shape nor form claims that DNA nor its use? In other words, there is no DNA "preemption" issue of any kind."

Whether the case *as presented at the trial court and Federal Circuit* provides basis for presentation of the *Questions Presented* as posed above is unclear. Assuming, *arguendo,* that there is no problem with the record as established below, then if the proposed *Questions Presented* could go forward, *amici* participation at the *certiorari* stage should be applauded.

But, to the extent that the hypothetical *Questions Presented* are *not* the basis for going forward, then the question is raised whether *amici* are well served by joining this case at the *certiorari* stage. It must also be remembered that patentees and patent applicants who *do* reach the merits stage are more frequently than not the losers of the resultant decision, particularly in patent-eligibility cases (as seen from the chart at page 5). No final decision needs to be made by a prospective *amicus* party at present, because *amici* joining at the *certiorari* stage do so after the petition is filed.

To the extent the Supreme Court grants *certiorari*, *amici* participation at the merits stage would then be welcomed. Then, the Court could venture into uncharted patent waters which have been the exclusive province of the courts of appeal. *See* § II, *Opening Uncharted Patent Waters to the Court.*

At first blush, one may wonder *how* it was possible for the Federal Circuit to reach the conclusion that it did, given the underlying facts of the case. *See* § III, *The Facts Establish a Patent-Eligible Invention.*

Given the publicity and importance of the case, the issue is whether prospective *amici* <u>*should*</u> participate at the Supreme Court? If so, when is the appropriate time to do so? *See* § V, *Whither Amici Participation.* Certainly, there are serious dangers raised for the patent community if this case is taken for review by the Supreme Court, including a potential for a binding, precedential Supreme Court affirmance of the Federal Circuit decision.

At least as important as the impact on the instant patent-eligibility issue is the fact that several long standing doctrines at the Federal Circuit have never been tested at the Supreme Court could in the wake of a merits review, here, wind up at the highest court. *See* § V-A, *Dangers of Amici Participation at the Petition Stage.* While caution and restraint in terms of *amici* participation at the *certiorari* petition stage is an appropriate course to take, *if* and when *certiorari* is granted in this case, at that time there is nothing to lose: To the contrary, at the merits briefing stage the participation of *amici* can be most important. *See* § V-B, *Positive Impact of Participation at the Merits Stage.*

If *certiorari* is denied, the door remains open for a challenge in a case with similar facts at the Patent Trial and Appeal Board in a Post Grant Review. While the negative ruling in *Sequenom* may force the case to go to the Federal Circuit, a panel may well be able to *distinguish* the current case or, if necessary, a party may seek *en banc* review to successfully overturn *Sequenom.* Either option is far better than if the Supreme Court ends up taking and affirming the *Sequenom* case which would then complicate matters.

Some have the thought that the Federal Circuit seems to be a "dead end" for the issues in this case, so, why not take a shot at the Supreme Court? This is a very dangerous attitude, given the fact that the Supreme Court rarely hears a patent case and when it does it is generally against the patentee, particularly in the area of patent-eligibility challenges under 35 USC § 101:

Supreme Court Patentability/Validity Decisions since 1952 (§§ 101-103, 112)

pro-patentee **anti-patentee**

Case	101	102	103	112
Hazeltine Research v. Brenner, 382 U.S. 252 (1965)				
United States v. Adams, 383 U.S. 39 (1966)				
Graham v. John Deere, 383 U.S. 1 (1966)				
Brenner v. Manson, 383 U.S. 519 (1966)				
Anderson's-Black Rock v. Pavement Salv., 396 U.S. 57 (1969)				
Gottschalk v. *Benson*, 409 U.S. 63 (1972)				
Dann v. Johnston, 425 U.S. 219 (1976)				
Sakraida v. Ag Pro, 425 U.S. 273 (1976)				
Parker v. *Flook*, 437 U.S. 584 (1978)				
Diamond v. Chakrabarty, 447 U.S. 303 (1980)				
Diamond v. Diehr, 450 U.S. 175 (1981)				
Pfaff v. Wells Electronics, 525 U.S. 55 (1998)				
J.E.M. Ag Supply v. Pioneer, 534 U.S. 124 (2001)				
Bilski v. Kappos, 561 U.S. 593 (2010)				
Microsoft Corp. v. i4i, 131 S.Ct. 2238 (2011)				
Mayo v. Prometheus, 132 S. Ct. 1289 (2012)				
Myriad case, Ass'n Mol. Path. v. Myriad, 133 S. Ct. 2107 (2013)				
Nautilus v. Biosig Instruments,134 S.Ct. 2120 (2014)				
Alice v. CLS Bank, 134 S. Ct. 2347 (2014)				
+ **TOTAL NUMBER IN THIS CATEGORY:**	**11**	**2**	**5**	**1**
+ **as % OF ALL CASES**	**58**	**10**	**26**	**5**
% PATENT APPLICANT/PATENTEE WINS	**27**	**50**	**20**	**0**

II. OPENING UNCHARTED PATENT WATERS TO THE COURT

It will be recalled that beginning with following *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), and *Diamond v. Diehr*, 450 U.S. 175 (1981), and with the exception of *J.E.M. Ag Supply, Inc. v Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001), there had been nearly three full decades of peace in the patent-eligibility arena, but following *Bilski v. Kappos*, 561 U.S. 593 (2010), there has been a stream of negative rulings denying patent-eligibility in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)(a method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder); the *Myriad* case, *Ass'n for Molecular Pathology v. Myriad Genetics., Inc.*, 133 S. Ct. 2107 (2013)("[a]n isolated DNA coding for a BRCA1 polypeptide"); and *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014)(a computerized scheme for mitigating "settlement risk").

The danger posed by grant of review in *Sequenom* poses potentially great risks for the pharmaceutical industry. Perhaps the gravest danger to unsettle the pharma field would be a review of the law of nonobviousness of pharmaceutical compounds established more than fifty years ago in *In re Papesch*, 315 F.2d 381 (CCPA 1963), but never tested at the Supreme Court. *See In re Dillon*, 919 F.2d 688, 696 (Fed. Cir. 1990)(en banc)(Lourie, J.)(discussing *Papesch*). To be sure, the *Myriad* case at first blush appears to present similar issues, but the question of obviousness of a particular low molecular weight molecule was not at all in issue.

III. THE *FACTS* ESTABLISH A PATENT-ELIGIBLE INVENTION

To be sure, the invention in the *Sequenom* case is surely a meritorious and patentable invention. In particular, it is impossible to say anything other than that the *claimed invention* is unobvious: Imagine, creation of a blood test to determine fetal DNA when the state of the art had required a womb-invasive sampling of fluid within the amniotic sac of the mother. First of all, it is clear that when the invention *as a whole* is considered including the limitations of "all elements", there is no realistic way to conclude any way other than that the invention is patent-eligibile. *See* § III-A, *The Invention "As a Whole" is Patent-Eligible.* Even disregarding this important point, whereas DNA is mentioned in the claims, the DNA is the object of identification and neither claimed nor part of a method of use. *See* § III-B, *Identifying the Presence of Certain DNA.* But, these two points represent the reality of the factual setting of the case, and not the reality of how the case was decided.

A The Invention "As a Whole" *is* Patent-Eligible

First of all, the invention *as a whole* – considering "all elements" of the claimed invention – is clearly novel and nonobvious and, *a fortiori* "inventive." It is against more than a century of Supreme Court case law to dissect a claim to a combination to consider each element as a separate entity.

As explained in *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[.]" 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)).

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')."

B. Identifying the Presence of Certain DNA

Secondly, and perhaps more importantly from the standpoint of patent-eligibility, the process claimed to *identify* certain known DNA does not in any way involve a claim to the DNA, *per se*, nor to a method of use of DNA. Rather, the DNA involved in the claimed invention is the *object* of *identification* to determine the presence of certain DNA. The Number One concern of the Supreme Court in considering whether an invention is patent-eligible is whether it does or does not "preempt" research or future use of the DNA. Quite clearly, *known* DNA is the object of the identification test claimed by Sequenom: There is no possible preemption of any use of the DNA based upon the claimed invention.

Just as a "microscope" can be used to identify the makeup of biological samples, the Sequenom invention in the *Ariosa* case provides a method to *identify* certain DNA. The *Ariosa* case has nothing to do with making, using or modifying DNA or creating brand new DNA, but, instead, the *Ariosa* case provides a pioneer genetic test to *identify* the presence or absence of specific, known DNA to see whether a fetus has such DNA, Remarkably, the test involves a blood test can be made based upon a simple blood sample drawn from the pregnant mother's arm –

as opposed to the classic, invasive amniocentesis involving invasion of the womb to collect a serum sample.

Sequenom is thus an invention to *identify* DNA contained in amniotic fluid but where the identification can be made without amniocentesis. As a method of identification of material in a sample, the invention in the *Ariosa* case may be analogized to a biotechnology "microscope" to identify the presence or absence of DNA.

The Sequenom invention thus provides a novel pre-natal test to *identify* paternal DNA from a blood test that is based upon blood drawn from a pregnant mother's arm, a breakthrough from the prior art womb-invasive collection of fluid through amniocentesis.

As defined by claim 1, the Sequenom invention involves a test "performed on a maternal serum or plasma sample from a pregnant female" that, for example, is directly drawn from the mother's arm as with any regular blood test, where the \method then involves "amplifyi[cation of] a paternally inherited nucleic acid from the serum or plasma sample" which takes an otherwise too sparse amount of the DNA to be sampled, when is then followed by "detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample."[*]

While the factual setting surely should lead to a conclusion of patent-eligibility, the reality is that the case turned on different issues: It is these different issues that form the legal predicate for any argument at the Supreme Court, and why this is a poor choice for a test case to reach the Supreme Court. *See* § IV, *A Unique Decision Departing from Key Facts*

IV. A UNIQUE DECISION DEPARTING FROM KEY FACTS

The Federal Circuit decision focused upon the fact that DNA is named in the claimed invention, without considering the fact that there is no claim to DNA, per

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[*]Claim 1: "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
amplifying a paternally inherited nucleic acid from the serum or plasma sample and
detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample."

se, nor to the use of DNA, nor the fact that the DNA in the process is merely the *object of identification*, and – as *known* DNA is clearly lacking patentability under 35 USC § 102 above and beyond the issue of patent-eligibility.

As to patent-eligibility, the prime concern of the Supreme Court patent-eligibility case law has been that a patent should not "preempt" future research or use of the DNA, but, here, such preemption is not possible. Thus, there was no "use" of DNA claimed, contrary to what is said by members of the court. *Ariosa Diagnostics , Inc. v. Sequenom, Inc.*, __ F.3d __, __ slip op. at 11 (Dec. 2, 2015) (Lourie, J., joined by Moore, J., concurring in den. reh'g en banc)("[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[.]")(original emphasis), *id.*, slip op. at 11 ("[I]f the concern is preemption of a natural phenomenon, this is, apparently, a novel process and that is what patents are intended to incentivize and be awarded for."); *id.*, slip op. at 14 (Dyk, J., concurring in den. reh'g en banc)(quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012), quoting *Parker v. Flook*, 437 U.S. 584, 594 (1978))("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.'")(emphasis added)

V. WHITHER *AMICI* PARTICIPATION

A. Dangers of Amici Participation at the Petition Stage

To be sure, a *petitioner* at the Supreme Court often clearly needs *amici* support to gain *certiorari*. Conversely, a potential *amicus* who does not want grant of review best plays his cards at the petition stage by standing pat: He should refrain from amicus participation as the more participation there is at this level, the more attention the Court will pay to the particular case, and therefore the greater the chance that four of the members of the Court will vote for review – the magic number for grant of *certiorari.*

To be sure, the *facts* of the Sequenom patent are compelling and cry out for a ruling of patent-eligibility. But, the *legal* ground for denial of patent-eligibility do not reflect an argument keyed to the "all elements" rule and, indeed, the above-quoted remarks of Circuit Judge Dyk show that that the case was viewed as one

involving "use of a natural law" whereas, in fact, the claimed invention is merely to *identify* certain DNA.

The dual factors of a failure of the appellate tribunal to understand the *Adams Battery* case and the "all elements" rule, coupled with the misunderstanding that the invention involves the use of the DNA all suggest that there is clear basis for a properly argued case to distinguish *Ariosa v. Sequenom* at the *en banc* level of the court. Quite clearly, even though *en banc* review is difficult, it is far, far easier to shape the law in this manner than butting heads at the Supreme Court where a patentee has a remarkably low chance of success.

More important from the standpoint of the pharmaceutical industry and potential *amici*, the question must be raised: Which is more important, seeking to play the long odds against a patentee prevailing at the Supreme Court *versus* opening a pandora's box to fresh consideration at the Supreme Court of the *Papesch* line of case law and other pharmaceutical patent issues?

B. Positive Impact of Participation at the Merits Stage

Conversely, at the *merits* stage once *certiorari* has been granted, at *that* point in time, *amicus* participation can be extremely important either from the standpoint of specific legal arguments that may be missed by the petitioner or by explaining the practical significance to a particular industry that will result from the Court's decision.

VI. A FUTURE TEST CASE COMING FROM A POST GRANT REVIEW

Assuming that *certiorari* is denied in *Sequenom*, this would leave the Federal Circuit decision outstanding. It would then be inevitable that a Post Grant Review proceeding will at some point in the near future be taken against a patent with facts similar to the *Ariosa* decision. Here, this represents perhaps the best chance to undo the damage of the *Ariosa* decision. In the first instance, a patent-knowledgeable decision is likely to be rendered by the Patent Trial and Appeal Board and, thereafter, there can be review at the Federal Circuit.

It may well be that the *Ariosa* decision can be distinguished, thereby avoiding the need for *en banc* review.

VII. CONCLUSION

Anyone who expects the Supreme Court to necessarily provide a nuanced approach to patent-eligibility should consider the sobering facts concerning the patent experience available to the Court.

Unlike the Federal Circuit which has several patent attorneys on the bench and where all but the newest members of the court have had a daily diet of patent cases and thus gained expertise on the bench, the Supreme Court has no patent attorney amongst its members nor does any of the members of the court have a long track record of hearing patent cases: Generally, there are only two or three patent cases at the Supreme Court per year. Unlike the Federal Circuit which has a staff of about fifty law clerks, most having a technical degree and patent expertise, none of the roughly forty law clerks at the Supreme Court has *any* patent experience.

While the current posture of the *Sequenom* case is negative, it remains to be seen how the petitioner fashions the *Question Presented* at the Supreme Court. Given that *amici* briefs are filed after the petition is filed, potential *amici* can have an open mind, today, and first await reading the *certiorari* petition to reach a final decision whether to file *amici* briefs in support of the petition.

INDEX

- A -

- B -

- C -

- D -

- E -

- F -

- G -

- H -

- I -

- J -

- K -

- L -

- M -

- N -

- O -

- P -

- Q -

- R -

- S -

- T -

- U -

- V -

- W -

- X Y Z -

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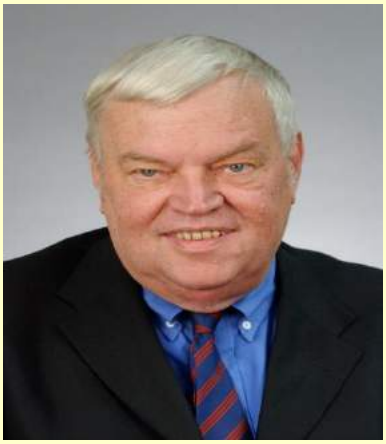
About the Author



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