33rd Annual Intellectual Property Law Conference

Has the Supreme Court’s “Implicit Exception” resulted in inventions in the biomedical field being held patent ineligible that otherwise would have proven patentable?

AND

Do the non-eligibility, statutory patentability requirements, if properly applied to such inventions, moot any justification for imposing an “Implicit Exception” barring patents directed to a natural law or phenomenon or other abstract idea/concept?

AND

Can various legislative proposals that have emerged to address patent eligibility be melded into a unitary approach to abrogate the Supreme Court’s “Implicit Exception”?

Or—

Whither patenting of biomedical inventions after Mayo, Myriad, and now Alice?

Robert A. Armitage
Consultant, IP Strategy & Policy

April 18-20, 2018
Arlington, VA
Introduction

The Supreme Court’s efforts to redirect jurisprudence governing fundamental elements of the patent law—through an array of notable decisions over the past two decades—have had profound consequences for inventors.¹ The Court’s efforts appear to have been grounded on its apparent belief that the 35-year legal stewardship of the patent law by the Federal Circuit had led the law astray—in key areas ranging from the stringency of the application of the non-obviousness standard² to the availability of injunctive relief³ to the most fundamental of all issues of patent law, the subject matter that can be considered eligible for patenting.⁴

The Court’s more frequent interventions to reinterpret the patent law have coincided with a vast increase in the sheer number of patents granted each year by the United States Patent and Trademark Office⁵ and the rise of the so-called “patent troll.”⁶ Thus, it is difficult to seriously dispute that the Supreme Court sees its contemporary role in the patent system as that of an essential counterbalance to the proclivities it sees within the Federal Circuit to effectuate a more inventor-friendly view of how the patent system might best discharge the constitutional purpose of the U.S. patent system to promote progress in the useful arts.

The Court’s interventions have perhaps been the most persistent and notorious in the recent efforts of the Court to more rigorously confine the subject matter that may be found eligible for patenting. In its work in this area of the patent law, the Court has been operating outside the patent statute itself—some would say countermanding the patent statute—with the judicial imposition of non-statutory limitations on patent eligibility. While the Court’s efforts to

¹ This paper, prepared for the ABA IPL Section’s 33rd Annual Spring IP Conference, will explore selected aspects of the topics set out in the description found in the program for the Conference, “As subject matter eligibility jurisprudence continues to develop in the wake of Supreme Court decisions such as Mayo, Alice, and Sequenom, there are growing concerns that worthy discoveries are being deemed ineligible, which may in turn be harming the incentive to innovate. This program will explore the state of subject matter eligibility law, including what types of inventions are being found eligible and ineligible; subject matter eligibility laws in other countries—how they compare to U.S. law, and how the disparities may (or may not) be affecting innovation and R&D investment in the US; and whether changes to the law are needed and, if so, what type of adjustments should be made.” This paper will largely confine its analysis and commentary to biomedical inventions that have been subject to patent-eligibility challenges.

⁶ As an example, the Electronic Frontier Foundation, among others, characterizes certain types of patent owners seeking to enforce the patent rights they own as “patent trolls” and has detailed what it sees as negative aspects of the patent assertion activities of these patent owners. The EFF sees the Supreme Court efforts, such as its Alice decision as a “rescue” effort. See https://www.eff.org/alice.
redirect the parameters of patent eligibility have been seen as a laudable exercise of judicial authority by some, these efforts have been roundly condemned by many of the patent system’s leading proponents, including those representing some of its most important constituencies.  

Some of the concern about the Supreme Court’s directives to the lower courts on patent eligibility has focused on biomedical-related inventions. Of all areas of patenting, a broad consensus exists that the availability of patents plays a key role in the ability to invest in the development and commercialization of new biomedical technology—and affording such develop/commercialize incentives is the prime economic justification for creating and maintaining a strong patent system.  

Whatever the field of technology to which an invention might relate, enough concern has been expressed over the role of Supreme Court jurisprudence on subject matter eligibility to have prompted efforts to seek redress through some form of legislative intervention. Indeed, as will be discussed in detail below, a collection of competing legislative ideas has now emerged for redressing these judicial-imposed limitations on patent eligibility. However, so long as there is a cacophony of approaches to a legislative remedy, it is unlikely that Congress will be able to find the type of consensus typically needed for significant patent reforms to become law.  

This paper will endeavor to review the current state of the Supreme Court law on subject matter eligibility for patenting. Given the outsized importance of patent eligibility issues to the biomedical community, the present effort will focus—as noted above—principally on biomedical-related inventions. This will include a review of recent Supreme Court and select lower court decisions relating to patent eligibility of biomedical inventions.  

From that focus, this paper will offer a number of tentative conclusions about the real-world consequences on biomedical patenting arising from the recent Supreme Court patent-eligibility mandates. Those conclusions will be used to suggest that the current judicial energy devoted to patent eligibility issue is misdirected and that the policy concerns that underlie them might be more rationally dedicated to reenergizing—and retooling—other aspects of the law on patentability and the law on patent claiming.

---

7 See David J. Kappos, This U.S. court decision just quashed innovation in health care, at http://fortune.com/2015/10/21/sequenom-ariosa-diagnostics-patent/, condemning the application of Supreme Court precedents in Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015).

8 As used herein, the term “biomedical” inventions is a reference broadly to the so-called “biotechnologies” that range from agricultural biotechnology to human diagnostic methods to methods of treating disease to more fundamental aspects of the modern—and more molecular—understanding of animal and plant genetics.

9 “Patent protection on these basic [biotechnology] inventions provides investors with the assurance that their investments are protected, and often provides the platform upon which a more diversified and robust R&D program can be funded and expanded. This is particularly true for the hundreds of small biotech start-ups on the cutting edge of biotechnology innovation. This innovation pipeline will in turn lead to subsequent domestic job creation in the area of agricultural biotechnology, creating thousands of new, high-paying American jobs in the process. Eliminating the very basic patents protecting inventions in this sector will undoubtedly have a negative effect on the availability of venture capital, decreasing the speed at which innovation will occur and the breadth of the potential R&D portfolio.” Sept. 9, 2010 Letter of James C. Greenwood, President and CEO, Biotechnology Industry Organization et al, to United State Department of Agriculture Secretary Vilsack, https://www.bio.org/sites/default/files/files/20100909.pdf.
The concluding portion of this paper sets out a comprehensive legislative proposal designed to bring harmony to the various approaches to reforming patent eligibility rules that have been recently tabled by leading patent system constituencies. The effort in this paper, by looking holistically at the issue of the needed boundaries on the availability of patent protection, proposes to abrogate the Supreme Court’s extra-statutory judicial eligibility rules in favor of a fully statutory law on patentability and patent claiming.

More specifically, this paper will conclude with a discussion of a collection of statutory changes to the patent law that have been calculated to amalgamate the various views that have been expressed by others on how best to limit patent eligibility. The unitary proposal that will be presented herein is premised on the assumption the predicate efforts of others must be respected and integrated in order to produce a consensus set of patent law changes. In short, thoughtful positions, previously tabled by leading voices in the patent community on needed restrictions on the subject matter that warrants protection through patents, simply must not be ignored.

That said, the challenge presented by the imperative to amalgamate this collection of differing proposals is by any measure formidable. They must be stitched together to form a single proposal capable of garnering the political consensus needed to legislate. A reasonable expectation going into any legislative effort is that the political challenges to achieving a successful outcome will be unrelenting and the margin for finding a workable, implementable consensus will be exceedingly narrow.

**The State of the Law on Subject Matter Eligibility: Biomedical Patenting Implications**

Recent Federal Circuit decisions underscore what some members of the court itself have lamented as the analytical futility of determining subject matter eligibility for patenting under recent Supreme Court precedents.

If constrained to define the state of U.S. patent eligibility law in a single word, for many in the patent community that word would be unsatisfactory. Against the background of over 200

---

10 Two Federal Circuit opinions are particular worthy of comparison, both by Judge Linn. See *Smart Systems Innovations, LLC v. Chicago Transit Authority*, App. No. 2016-1233 (October 18, 2017), J. Linn (dissenting) and *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, *supra*, J. Linn (dissenting in part and concurring in part).

11 “I join the court's opinion invalidating the claims of the [Sequenom] patent only because I am bound by the sweeping language of the test set out in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S.Ct. 1289, 182 L.Ed.2d 321 (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.” *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, at 788 F.3d at 1380 (J. Linn, concurring). “Because the majority's determination with respect to the representative claims … is consistent with past decisions finding ineligibility, I concur with that part of its decision, not because the inventions covered by the claims do not deserve patent protection but because I am bound by precedent to reach that conclusion.” *Smart Systems Innovations, LLC v. Chicago Transit Authority*, *supra*. (J. Linn, dissenting in part and concurring in part).
years of statutory stability in setting out a standard for subject matter eligibility for patenting, the Supreme Court has recently elected to reinvigorate its non-statutory adjunct to the statutory eligibility standard by specifying a two-part test (sometimes called “Mayo/Alice test”) that must be satisfied for a claimed invention to be patent eligible. The two-part test assesses first if a claimed invention is directed to a law/product of nature, natural/physical phenomenon, or an abstract idea or concept and, if so, then determines if the claimed invention adds significantly more, specifically some inventive concept.

The most pointed criticism of the Court’s implicit exception is that the Court’s recent jurisprudence has expanded the reach of the exception, such that today it applies to invalidate U.S. patents that would be clearly eligible for patenting under international norms. Without question, the United States patent system potentially pays an enormous price as a result of the complexity, subjectivity, unpredictability, and distressing analytical futility of determining subject matter eligibility for patenting under the Supreme Court’s Alice/Mayo two-part test, particularly if it represents a largely a needless burden that is unnecessary to vindicate any articulated policy objective for imposing this non-statutory requirement. Indeed, the two-part test has been cited the root cause for the contention that the United States has compromised its global standing as a leader in developing and administering highly effective patent laws.

Other criticisms of the Court’s recent jurisprudence have centered on the mechanics of the two-part analysis that the Court has established for determining if a claimed invention in a patent is to be rendered invalid because it is directed to a law of nature, natural phenomenon, or abstract idea. While its generalized nature is judicially justified because it affords as a

12 35 U.S.C. § 101 under the 1952 Patent Act requires that a valid claim must be drafted in terms of a “process, machine, manufacture, or composition of matter” or an improvement thereto. The statutory limitation on patenting to these four categories has remained essentially unchanged since the 1793 Patent Act, when Congress provided that patents would be available only for “any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter . . . .” Patent Act of 1793, Ch. 11, 1 Stat. 318-323 (February 21, 1793).


14 “We have described step two of [the implicit exception] analysis as a search for an ‘inventive concept’—i.e., an element or combination of elements that is ‘sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.’” Alice Corp. Pty. Ltd. v. CLS Bank Int’l, supra, at 134 S. Ct. 2355 (alterations in original) (quoting Mayo, supra, at 132 S. Ct. 1294).

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


sufficiently malleable tool to blunt patent “drafting” techniques that otherwise might circumvent a more direct bar to patents dominating “abstract ideas” or other concepts, the result is a bar to patenting that is potentially wide ranging—since nearly all inventions have associated ideas upon which they are based.

The Court apparently intends that its sweeping analytical framework will operate as a surrogate for addressing a broader policy imperative: How to assure that a valid patent claim not be so conceptual that rights under the patent might dominate or otherwise preempt access to a law or product of nature, a natural phenomenon, or an abstract idea. The Court has expressed concerns that the assertion of such a conceptual—and preemptive—patent claim, by impairing access to basic tools of science and technology, could impede, rather than promote, progress in the useful arts.

Like many surrogate tests, it risks overreaching its targeted policy objective. This risk is magnified when the implicit exception is applied as a “threshold test.” For example, repeatedly in recent years, the two-part test has been applied through a summary judgment motion, before any other aspect of the patentability of the claimed invention has been assessed.

Not knowing if one or more of the remaining statutory patentability requirements would invalidate a patent claim, the tendency is to stretch the threshold test’s application to assure a potentially problematic claim is invalidated—lest such a claim might otherwise survive as valid under the explicit statutory requirements.

Moreover, and most significantly, in applying such a non-statutory limitation as a threshold consideration, e.g., as a tool to be applied in a pre-trial summary judgment setting, it inherently operates without considering whether or how the present, explicit statutory framework, taken as a whole, may operate to routinely invalidate any conceptual patent claims that would also fail the two-part test.

18 “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 (alterations in original) (quoting Mayo, 132 S. Ct. at 1297).
19 “[T]he Court’s precedents . . . warn us against upholding patents that claim processes that too broadly preempt the use of a natural law.” Mayo, 132 S. Ct. at 1294.
20 “[M]onopolization of [the basic tools of scientific and technological work] through the grant of a patent might tend to impede innovation more than it would tend to promote it.” Id. at 1293.
21 Bilski v. Kappos, supra.
22 “This appeal is from a grant of summary judgment of invalidity of the asserted claims . . . . The United States District Court for the Northern District of California found that the asserted claims . . . are not directed to patent eligible subject matter and are therefore invalid under 35 U.S.C. § 101. For the reasons explained below, we affirm.” Ariosa Diagnostics, Inc. v. Sequenom, Inc., supra, at 788 F.3d 1373.
23 Indeed, the Court’s jurisprudence itself assumes some overlap between the implicit exception and the statutory doctrines limiting patents. “[T]he § 101 patent eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap. But that need not always be so. And to shift the patent eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.” Mayo, 132 S. Ct. at 1304.
However, to date, the Court has never fully considered whether the proper interpretation of the current statutory requirements, considered together rather than piecemeal, would fully address the policy considerations that caused the Court to impose its non-statutory implicit exception. This omission in the Court’s thinking is more than just regrettable.

Given the potential of the Mayo/Alice test for undermining the effectiveness of the patent incentive in unjustifiable ways, it would seem essential to explore—and wrestle to the truth—whether the explicit statutory requirements now present in Title 35, United States Code, appear able to render unnecessary any judicially imposed, extra-statutory, implicit rule against the patenting of a law/product of nature, natural/physical phenomenon, or other abstract idea or concept. This paper, therefore, will next explore this hypothesis—referred to in this paper as the redundancy hypothesis—which can be restated as follows: To the extent the explicit statutory conditions and requirements for patentability—when they are properly interpreted and applied—bar securing valid patents that might prevent access to any law or product of nature, any natural phenomenon, or any abstract idea or other mere concept, such explicit requirements already in the patent statute self-evidently moot the need for any judicially imposed implicit ones.

As yet, the redundancy hypothesis has not been empirically tested through an analysis of patent claims from reported decisions of the courts in the post-Bilski era. One way to assess the validity of the hypothesis is to ask and answer a pair of simple questions. Does the “implicit exception” in actual practice do no more than routinely declare ineligible claimed inventions that would likely be found unpatentable in any event applying the non-eligibility requirements for patentability? Alternatively, are there decided cases where “implicit exception” ineligibility holdings have invalidated claimed inventions that were—or likely would have been—found to be fully patentable otherwise? To the extent that respective answers to these two questions are a simple “yes” and “no,” the redundancy hypothesis posited above would appear to have clear and undeniable merit.

Such redundancy, if established, presents a powerful argument for abrogation of the duplicative test given the abundant criticism of its operation. At a minimum, the proponents for continuing the application of a demonstrably redundant two-part test would be left with the burden for justifying the maintenance of this extra-statutory standard. Meeting that burden would require, at a minimum, the identification of offsetting sufficient virtues.

In this regard, proponents for the two-part test often cite to its asserted procedural expediency. Even if the two-part test operates as nothing more than a faithful (albeit redundant) mimic of the non-eligibility statutory patentability requirements, proponents of the two-part test laud its supposed amenability to summary determination in patent infringement litigation.25 Any

---

24 The Supreme Court was urged to address precisely this question in the Lilly, et al. amicus brief in Ariosa Diagnostics, Inc. v. Sequenom, Inc., supra, available at http://www.scotusblog.com/wp-content/uploads/2016/04/15-1182-Amicus-Brief-of-Eli-Lilly-et-al..pdf: “Given the current explicit statutory limitations on patenting in the Patent Act—and the proper interpretation of those limitations—should the Court’s judicially imposed implicit exception to subject matter considered to be eligible for patenting be abrogated, such that patentability and patent validity are to be determined solely under such explicit statutory provisions?” Question Presented at p. i.

25 Recent Federal Circuit jurisprudence indicates that the “implicit exception,” even if often fodder for summary disposition, cannot be decided summarily as a matter of routine. See Steven E. Berkheimer v. HP Inc., fka...
effort at justifying an abrogation of the two-part test would likely need to address the extent to which any replacement standard that would impose limits on enforceable patent rights could offer a comparable level of procedural expediency for accused infringers faced with invalid patent claims.

To validate the redundancy hypothesis would require a comparative examination of how the courts have applied Mayo/Alice to find patent claims ineligible and assess the extent to which such patent-ineligible claims would have, in any event, failed to survive as valid under the remaining, non-eligibility requirements for patentability in the patent statute. For the present purposes this analysis will proceed with a vetting of how the “implicit exception” jurisprudence applies with particular reference to judicial holdings in the appellate courts involving only biomedical-related patents. The present task is simplified given the relatively few such judicial holdings that have been rendered in the aftermath of the decisions addressing biomedical claims in Mayo and Myriad.

The following summarizes the key judicial developments at the Federal Circuit on the “implicit exception” issue since the Supreme Court’s decisions in Mayo, Myriad, and Alice and identifies the court’s five reported eligibility-related decisions that are biomedical-related:

- In 2014, the most notable Federal Circuit post-Alice decisions came in a November 14, 2014 Internet-distribution-related decision, Ultramercial, Inc. v. HULU, LLC, 772 F. 3d 709 (Fed. Cir. 2014), and a December 5, 2014 web-page-related decision, DdR Holdings, LLC v. Hotels. Com, LP, 773 F.3d 1245 (Fed. Cir. 2014). While neither of these decisions related to a biomedical invention, a third 2014 Federal Circuit holding did, i.e., In re BRCA1- & BRCA2-Based Hereditary Cancer Test, 774 F. 3d 755 (Fed. Cir. 2014), discussed in more detail below.

- By far—at least in the biomedical arena—the most significant Federal Circuit decision on patent eligibility in 2015 was Judge Reyna’s Sequenom holding that was referenced above and will be discussed in detail below. This decision stands today as Federal Circuit precedent, notwithstanding a concerted campaign led by 22 amici in support of the grant of certiorari that was unsuccessful in getting the Supreme Court to consider the appeal.

Hewlett-Packard Company, App. No. 2017-1437 (Fed. Cir. February 8, 2018) at slip op. 12, noting that the “question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact.” The need for fact finding may limit the ability for the two-part test’s “inventive concept” determination from being decided via summary judgment, i.e., “While patent eligibility is ultimately a question of law, the district court erred in concluding there are no underlying factual questions to the § 101 inquiry. … Whether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination. Whether a particular technology is well-understood, routine, and conventional goes beyond what was simply known in the prior art. The mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional.” Slip op. at 14.

26 The present analysis is confined to decisions of the Supreme Court and the Federal Circuit for which further judicial review is no longer possible. It does not extend to district court decisions, except for a single decision that is footnoted below.

By 2016, Federal Circuit decisions on patent eligibility issues had become routine, with the court issuing no less than 15 precedential opinions on patent eligibility. The notable biomedical-related opinions were those by Judge Dyk in *Genetic Technologies* and by Chief Judge Prost in *CellzDirect*, both examined below. Like Judge Reyna’s decision in *Sequenom*, Judge Dyk found claims in *Genetic Technologies* to be patent ineligible. In contrast, Chief Judge Prost declined to find the claimed inventions patent ineligible under the *Mayo/Alice* two-part test.

In 2017, the number of precedential opinions by the Federal Circuit was slightly fewer than the 2016 mark, with the Federal Circuit addressing patent eligibility a dozen precedential decisions. Ten decisions were related to computer-implemented (i.e., software-related) inventions. An eleventh decision involved a claim construed sufficiently broadly to encompass “carrier waves,” such that the court determined the claim to be directed to a patent-ineligibility “signal.” A twelfth decision, *Cleveland Clinic*, was another biomedical-related decision, again by Judge Reyna, that found a biomedical invention ineligible for patenting. Its holding is detailed below.

**Patentability Otherwise of Biomedical Claimed Inventions Found Ineligible Since Bilski**

The analysis below will focus on six patent ineligibility holdings and a single holding of patent eligibility among the biomedical-related decision referenced above, i.e., the five post-*Alice* Federal Circuit decisions *In re BRACA1 & BRACA2, Sequenom, Genetic Technologies, CellzDirect, and Cleveland Clinic* and the two predicate Supreme Court holdings in *Mayo* and *Myriad*. This focus will provide a basis for drawing at least a tentative conclusion on the validity

---


29 Besides *Genetic Techs., Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016) and *Rapid Litigation Management Ltd. v. CellzDirect*, 827 F. 3d 1042 (Fed. Cir. 2016), the majority of the 2016 Federal Circuit decisions related to computer-implemented (i.e., software-related) inventions. Among the most notable were: *In re TLI Communications LLC Patent Litigation*, 823 F. 3d 607 (Fed. Cir. 2016); *Bascom Global Internet Services v. AT&T Mobility*, 827 F. 3d 1341 (Fed. Cir. 2016); *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016); *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350 (Fed. Cir. 2016); *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138 (Fed. Cir. 2016); *McRO, Inc. v. Bandai Namco Games America Inc.*, 837 F.3d 1299 (Fed. Cir. 2016); *Intellectual Ventures I, LLC v. Symantec Corp.*, 838 F.3d 1307 (Fed. Cir. 2016); and *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288 (Fed. Cir. 2016).

30 The reported decisions from 2017 were *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017); *Smart Systems Innovations, LLC v. Chicago Transit Authority*, App. No. 2016-1233 (Oct. 18, 2017); *Credit Acceptance Corp. v. Westlake Services*, 859 F.3d 1044 (Fed. Cir. 2017); *Intellectual Ventures I LLC v. Capital One Financial Corp.*, 850 F.3d 1332 (Fed. Cir. 2017); *Intellectual Ventures I LLC v. Erie Indemnity Co.*, 850 F.3d 1315 (Fed. Cir. 2017); *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275 (Fed. Cir. 2017), panel rehearing and rehearing en banc denied, 870 F.3d 1298 (Fed. Cir. 2017); *RecogniCorp, LLC v. Nintendo Co.*, 855 F.3d 1322 (Fed. Cir. 2017); *Return Mail, Inc. v. United States Postal Service*, 868 F.3d 1350 (Fed. Cir. 2017); *secured Mail Solutions LLC v. Universal Wilde, Inc.*, 873 F.3d 905 (Fed. Cir. 2017); *Thales Visionix Inc. v. United States*, 850 F.3d 1315 (Fed. Cir. 2017); *Two-Way Media Ltd. v. Comcast Cable Communications, LLC*, 874 F.3d 1329 (Fed. Cir. 2017); and *Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253 (Fed. Cir. 2017).

of the redundancy hypothesis, i.e., the proposition that the Supreme Court’s “implicit exception” jurisprudence has been essentially redundant with respect to the non-eligibility, statutory requirements for patentability.

By way of preface, the analysis below largely affirms the redundancy hypothesis. It suggests that the Supreme Court’s new eligibility standard has not inflicted any discernable incremental loss in biomedical-related subject matter that can be validly patented. Thus, this analysis standing by itself, offers no support for a conclusion that the Mayo/Alice jurisprudence represents a compelling reason for reducing or halting new investments in the development and commercialization of new biomedical technology based on the unavailability of valid patent protection that otherwise could have been secured.32

1. **Mayo v. Prometheus: Patent Ineligibility of an Errantly Constrained Claim?**

The prototype claim33 of the Prometheus patent in Mayo v. Prometheus, had it been properly construed by the court, should have been found to contain two—and only two—non-abstract steps. These were the “administering” step and the “determining” step below:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per $8 \times 10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per $8 \times 10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Had the Prometheus claim been properly construed, the above text from the claim that follows the recited two steps in the claim (italicized above) should have been interpreted as a pair of non-consequential “wherein” clauses. Indeed, these “wherein clauses” can be best understood as “do nothing” clauses. They merely suggest how the data generated from the second of the two steps should be interpreted. They do not on their face require data interpretation.

---

32 For the purposes of making the non-eligibility patentability analyses below, a number of observations and conclusions will be expressed on a non-eligibility patentability issues for patent claims from reported decisions. These conclusions, even if expressed herein in unequivocal terms, should be understood by the reader to reflect only an invalidity contention that could be plausibly asserted and could plausibly succeed. Thus, the observations and conclusions that follow are not intended to reflect a legal conclusion on the validity or invalidity of any patent claim, even if so expressed, e.g., they are not intended to reflect the prospect for clear and convincing evidence to be marshalled to overcome the presumption that any particular claimed invention, as properly construed under the canons of claim construction, is valid.

33 Claim 1 of U.S. Patent 6,355,623.
Specifically, the “wherein” clauses specify no act that must be performed to infringe the claim. In this regard, there is no “third step” set out in the claim that requires that data obtained from the second step of the claim to be acted upon.

Faced with this (at best) unfortunately drafted claim, the Federal Circuit—rather than simply throwing up its hands—accepted the district court’s claim construction that, as a matter of law, the wherein clauses should be understood as a third (and mental) step to be performed before the claim could be infringed. One might reasonably postulate that this bad claim construction in Mayo opened the door to the Supreme Court decision making bad patent eligibility law. Indeed, had the claim been properly interpreted as limited to only its two explicit steps only, the limitation of the claim to two concrete and physical steps should have immunized the claim from an attack on eligibility grounds.

Taken by themselves, a claim limited to these two steps is simply a conventional method of treatment (“a new way of using an existing drug”) claim. Properly construed, step (a) simply requires treating a patient with a drug who under step (b) must then submit to further testing. Together the two steps define what is purportedly “new” in the way of using the drug. In Mayo itself, the Supreme Court saw claims to such “a new way of using an existing drug” to epitomize patent-eligible subject matter—or, at a minimum—to be readily distinguishable from patent-ineligible subject matter.

However, given proper claim construction, it becomes hard for a trained patent draftsman to see how the two-step claim makes sense, at least if the claim was intended to define patentable subject matter, eligibility aside. When properly construed, this manifestly patent-eligible claim appears to lack any prospect of being novel and, thus, patentable. Indeed, as discussed below, the very breadth of the claim would appear to doom any prospect for the claim being found novel.

Administering a drug and then testing a patient to determine the blood level of the administered drug (which is all that the claim requires to be infringed, if properly construed) represent two steps that would necessarily have been sequential activities performed in the prior art—at a point long before the time at which the medicine had completed the required clinical

34 “[T]he claims have three steps: (1) administering the drug to a subject, (2) determining metabolite levels, and (3) being warned that an adjustment in dosage may be required. … We agree with the district court that the final ‘wherein’ clauses are mental steps and thus not patent-eligible per se. However, although they alone are not patent-eligible, the claims are not simply to the mental steps.” 628 F.3d at 1352 and 1358.

35 The policy rationale cited by the Supreme Court collapses once the do-nothing wherein clauses are properly understood as non-limiting as to any further, post-measurement act by the physician, “The laws of nature at issue here are narrow laws that may have limited applications, but the patent claims that embody them nonetheless implicate this concern. They tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe. In doing so, they tie up the doctor’s subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations.” [Emphasis supplied.] 132 Sup. Ct. at 1302.

36 “Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws. 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, while eliminating any temptation to depart from case law precedent.” 132 Sup. Ct. at 1302.
testing need for the medicine to be approved for marketing. The second step would be a necessary accompaniment to the first step during the course of any determination of bioavailability of the drug administered in the first step. In brief, the two-steps describe a prior art process needed to develop the drug.

In sum, the Prometheus claims in the Mayo decision—had they been properly construed—should have been found to lack novelty and, thus, not to define any patentable subject matter. Given that same proper construction, the claims should have been found to have been confined to patent-eligible subject matter. As noted above, the Supreme Court admitted as much, albeit in dicta.37

As a result, as regrettable as the Mayo jurisprudence might be in setting an ineligibility precedent, it is not possible to conclude that the Supreme Court invalidated on eligibility grounds—using its “implicit exception” doctrine—a claimed invention that otherwise would have been patentable under the statutory patentability requirements. Thus decision is, thus, fully consistent with the redundancy hypothesis.

The lesson from the Mayo v. Prometheus decision relates more to the perils of bad claim drafting practices and the potential for unforeseen and unfortunate consequences. Really bad claiming practices coupled with an unforgivably bad claim construction can spawn a tragically bad precedent on patent eligibility.

2. **Myriad: Claims Manifestly Unpatentable, Even Absent Mayo/Alice?**

In the Myriad appeal, the Supreme Court focused on claims 1, 2, 5, and 6 of Myriad’s ‘282 patent as being representative of the numerous claims in the three Myriad patents before the Court.38 The claims considered by the Court were as remarkably broad as they were remarkably terse:

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.
   ...
3. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.
4. An isolated DNA having at least 15 nucleotides of the DNA of claim 2.

Three passages from the Myriad patent specification are particularly relevant to understanding the utter breadth of these claims—as well as the issues such a pathological breadth

---

37 See the immediately preceding footnote.
38 “At issue are claims 1, 2, 5, 6, and 7 of U.S. Patent 5,747,282 (the ‘282 patent), claim 1 of U.S. Patent 5,693,473 (the ‘473 patent), and claims 1, 6, and 7 of U.S. Patent 5,837,492 (the ‘492 patent).” 133 S. Ct. 2113.
inevitably creates for their non-eligibility patentability. The salient aspects of what the patent teaches about the claimed invention are described in the three bullet points below:

- “Combination of sequences obtained from cDNA clones, hybrid selection sequences, and amplified PCR products allowed construction of a composite full length BRCA1 cDNA (SEQ ID NO:1)”.
  
  The reference to “cDNA” or “complementary DNA” is a reference to a type of a man-made DNA compound in which the nucleotide sequence in the DNA compound is synthesized using man-made techniques, often done in man-made cells. Claim 2 above is alone restricted to this type of cDNA and excludes “genomic DNA”—i.e., DNA that contains nucleotides sequences identical to those found in the human genome. Thus, claim 2 excludes the intact BRCA1 gene DNA that can be found within the nucleotide sequence of human chromosome 17, i.e., the chromosome where the gene is located. On account of its entirely man-made character, claim 2 is the only Myriad claim found eligible for patenting.

- “The coding sequence for a BRCA1 polypeptide is shown in SEQ ID NO:1, with the amino acid sequence shown in SEQ ID NO:2.”

  In contrast to claim 2, claim 1—by referencing any DNA corresponding through the “genetic code” to the amino acid sequence of SEQ ID NO:2—encompasses on any DNA compound with a sequence that codes for the BRCA1 gene, including the identical sequence found in genomic DNA, such as the DNA compound represented by human chromosome 17, where the BRCA1 gene is located.

- “Isolated” DNA as defined by the Myriad patents simply means DNA “substantially separated from other cellular components which naturally accompany a native human sequence or protein, e.g., ribosomes, polymerases, many other human genome sequences and proteins. The term embraces a nucleic acid sequence ... which has been removed from its naturally occurring environment ....”

  The two-part definition for “isolated” was clearly drafted to give the Myriad claims a broad sweep, particularly in light of the second sentence quoted above. Indeed, “isolated DNA” under the patent’s definition appears to include any DNA-containing material to be found outside the nucleus of the cell in which the DNA is natively housed, so long as the structure of the DNA material at least in part includes the nucleotide sequence specified in the claims. Thus, simply removing chromosome 17 (which is a “DNA sequence”) from the nucleus of a human cell would constitute “isolated” DNA.

  As noted above, the Supreme Court determined that, being directed to cDNA, claim 2 was not ineligible for patenting. However, claim 1, being broad enough to encompass a DNA compound containing the identical DNA sequence to that of the genomic DNA sequence for the BRCA gene was patent ineligible. Because independent claims 5 and 6 were even broader than ineligible claim 1 (i.e. only requiring a subset of the entire nucleotide sequence coding for the human BRCA1 gene), the patent eligibility holding of claim 1 a fortiori applied to these claims.

39 Col. 53, lines 4-7, ’282 patent.
40 Col. 19, lines 47-50, ’282 patent.
In reaching this conclusion on eligibility-based unpatentability, the Supreme Court appears to have misunderstood just how broad Myriad patent rights were in claims 1. Had the Court focused on the breadth of the claims as revealed by the salient aspects of the patent specification, the Court might well have taken notice of the fact that claims 1, 5, and 6 had no possibility of being novel.

According to the Court, “Myriad’s patents would, if valid, give it the exclusive right to isolate an individual’s BRCA1 and BRCA2 genes (or any strand of 15 or more nucleotides within the genes) by breaking the covalent bonds that connect the DNA to the rest of the individual’s genome.” As noted above, however, Myriad’s rights in these claim were, if valid, broad enough to have prevented intact human chromosome 17 from being removed from the intact nucleus of any human cell. In other words, Myriad’s claim were broad enough to prevent relevant prior art from being practiced.

In the prior art, this type of “isolation” of chromosome 17 had been done repeatedly for decades and decades before Myriad’s supposed invention. As an example, with respect to claims 5 and 6, human chromosome 17, once freed from the nucleus of a human cell at that point “comprises” an “isolated DNA” with a sequence containing 15 or more BRCA1 gene-encoding nucleotides. With respect to claim 1, chromosome 17—again, once removed from the intact nucleus of a human cell—“comprises” the entire DNA sequence encoding the amino acids for the human BRCA1 gene.

The Court further missed the point that Myriad’s claims not only lacked novelty for the reasons set out above, but likely could not pass muster under the sufficiency of disclosure requirements for patentability under 35 U.S.C. § 112(a). Myriad’s claimed inventions that were based a “gene discovery” that for the first time permitted Myriad scientists to identify genetic material from human cells that revealed the nucleotide sequences encoding the human BRCA1 gene. With this information in hand, Myriad was able to prepare DNA compounds that contain 15 or more nucleotides containing this type of sequence information—as well as DNA compounds that could be used in recombinant cells to express the entire amino acid sequence for the gene.

However meritorious such a genetic discovery might be, it is not a “blank check” under the patent statute that can be written for any type of patent claim to a chemical compound “comprising” that newly identified DNA sequence information. As with any other inventions expressed in terms of new chemical compounds, the § 112(a) disclosure requirements bar

---

42 133 S. Ct. at 2113. The Court appears to have missed the point that no technology exists to make the precise snips to genomic DNA to actually isolate the intact DNA compound in the human genome that itself is used in the human body to encode any individual’s BRCA1 gene itself. Indeed, Myriad never asserted in its patents that isolating intact BRCA genes from an individual human cell could be done. What the Court suggests could be done has not been accomplished, even with the technology available today.

43 The above conclusion follows inescapably from the broad definition given to the term “isolated” by the Myriad specification and the open-ended “comprising” structure of the Myriad claims. By structuring the claims as open-ended “comprising” claims, the limitations as to nucleotide sequence at specify only a part—but not the whole—of the structure of the claimed DNA molecule. As a result, the claims’ scope extends to any molecule containing the specified DNA sequence irrespective of what other DNA sequences might be part of the molecule.
claiming a limitless number of distinct chemical compounds by specifying only part of the structure of the compound, while leaving the remainder of the structure open-ended and undefined.

The Supreme Court appears to have understood that the Myriad claims raised at least some sort of “red flag” by failing to provide a complete identification of the compounds being claimed, but the Court then failed to connect the red flag to that portion of the patent statute already barring a patent drafting technique with this type of open-ended character:

“[T]he claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes. If the 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 (such as claims 1 and 2 of the ‘282 patent) by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule ‘invented’ by Myriad. But Myriad obviously would resist that outcome because its claim is concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule.”"44

What the Court has laid out in the quote above, albeit unartfully, is what any student of the patent law would understand to be a lack of a sufficient § 112(a) “written description”—claiming compounds not invented. Indeed, because the claims that characterize only part of the structure of the vast number of compound being claimed—they cannot survive well-understood standards for a sufficient disclosure, both the “written description” and “enablement” requirements. Such claims are unavoidably invalid on overbreadth § 112(a) grounds.45

Claim 5, being limited compounds comprising a 15 or more nucleotide sequence within the BRCA gene additionally poses § 101/§ 112(a) utility issues—failure to enable a practical utility for the short snippets of DNA as required under 35 U.S.C. § 101.46 Thus, as with the

44 133 S. Ct. 2118.
45 As for the “written description” aspect, in Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (en banc), the Federal Circuit noted that the appealed “claims are . . . genus claims, encompassing the use of all substances that achieve the desired result of reducing the binding of NF-[κ]B to NF-[κ]B recognition sites.” Id. at 1341. In invalidating the claims under the § 112(a) “written description” requirement, the Federal Circuit noted that “[s]uch claims merely recite a description of the problem to be solved while claiming all solutions to it and . . . cover any compound later actually invented and determined to fall within the claim’s functional boundaries . . . .” Id. at 1353. The identical problem is present in any claim where the structure of a compound being claimed is only partially defined and the claim covers any and every compound where the undefined portion of the claim is effectively limited only to structures that would retain the disclosed utility for the claimed compound, i.e., the claim is effective functional in character.
46 The requirement for a practical use has been extensively developed by the Federal Circuit. See In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005), which followed the Supreme Court precedent in Brenner v. Manson, 383 U.S. 519 (1966). The Federal Circuit has held that the utility that must specific, practical, and substantial, but with the terms “practical” and “substantial” being considered synonymous. 421 F.3d at 1371, including footnote 4, “this court considered the phrase ‘practical utility’ to be synonymous with the phrase “substantial utility.”"
Prometheus claims, the Myriad claims could not have survived as valid even if the Court had found the claims to be patent eligible.

Again, bad claims appear to have been the motive force producing a bad result on the issue of patent eligibility. However, the result is entirely consistent with the redundancy hypothesis—the two-part test was applied in *Myriad* to find patent-ineligible claims that were otherwise unpatentable.

3. **IN RE BRCA1 & BRCA2: ANOTHER UNPATENTABLE INVENTION, EVEN IF ELIGIBLE?**

A good starting point for undertaking a close examination of the operation of the two-part test of *Mayo/Alice* for biomedical-related inventions can be found in claims 7 and 8 of U.S. Patent 5,753,441. The validity of these claims was contested in the appeal in *In re BRCA1- & BRCA2-Based Hereditary Cancer Test*, supra. As reported in the Federal Circuit decision, claim 8 reads (revised by the court to include independent claim 1 limitations):

A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises

- comparing germline sequence of a BRCA1 gene or BRCA1 RNA from a tissue sample from said subject or a sequence of BRCA1 cDNA made from mRNA from said sample with germline sequences of wild-type BRCA1 gene, wild-type BRCA1 RNA or wild-type BRCA1 cDNA,

  wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject,

  wherein a germline nucleic acid sequence is compared by amplifying all or part of a BRCA1 gene from said sample using a set of primers to produce amplified nucleic acids and sequencing the amplified nucleic acids.\(^{47}\)

---

\(^{47}\)Emphasis added. While this claim is nominally a one-step process, the terminal wherein clause actually specifies two additional steps to which the claim is limited because the “comparing” step is further limited through the “wherein” clause. Thus, a more accurate incarnation of the limitations in claim 8, that more explicitly sets out each of the actual steps that appear to be recited in the claim—and that affords a more complete preamble, would read:

A method for identifying differences in the sequence of the wild-type BRCA1 gene, wild-type BRCA1 RNA or wild-type BRCA1 cDNA sequence from the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA in a tissue sample obtained from a subject, which differences may indicate an alteration in the BRCA1 gene in said subject, which comprises

- amplifying all or part of a BRCA1 gene from said sample using a set of primers to produce the amplified nucleic acids;
- sequencing the amplified nucleic acids; and
- comparing the sequence of the amplified nucleic acids with the corresponding wild-type sequence to identify any differences.
The Federal Circuit, relying in part on its prior decisions, invalidated both diagnostic method claims 7 and 8 under the Supreme Court’s “implicit exception” using the following analysis keyed again to the breadth of protection that the claims purport to provide, particularly compared to the extent of the disclosure supportive of that claim breadth.48

[T]he comparisons described in the first [step] … are directed to the patent-ineligible abstract idea of comparing BRCA sequences and determining the existence of alterations. The methods, directed to identification of alterations of the gene, require merely comparing the patient’s gene with the wild-type and identifying any differences that arise. … The number of covered comparisons is unlimited. The covered comparisons are not restricted by the purpose of the comparison or the alteration being detected. Because of its breadth, the comparison step covers detection of yet undiscovered alterations, as well as comparisons for purposes other than detection of cancer. Even with respect to cancer, the comparisons are not limited to the detection of risk of breast or ovarian cancer. Similar concerns to the ones the Supreme Court expressed in Myriad with respect to isolated DNA exist here: allowing a patent on the comparison step could impede a great swath of research relating to the BRCA genes, and it is antithetical to the patent laws to allow these basic building blocks of scientific research to be monopolized.

Claims 7 and 8 of the ‘441 patent, although invalidated on eligibility grounds, would have been found unpatentable on § 112(a) non-eligibility grounds, again based upon their startling breadth and limited enabling disclosure. Indeed, it is difficult to imagine an argument under which the claims could have survived an invalidity attack on the ground of lack of enablement.

The Federal Circuit’s ineligibility rationale quoted above actually explains the basis on which the claims would have failed the patentability requirement under § 112(a). As noted in the Federal Circuit’s two-part test analysis, the invalidated BRCA1 diagnostic claims extend to identifying in a test sample any difference from the wild-type gene. In other words, the claims is broad enough to cover every difference detected from the wild-type gene, whatever the significance or insignificance of the difference, whether known or yet to be discovered.

Given this breadth of claiming, expert testimony would likely support a legal conclusion that undue experimentation would be required to determine, among all such differences, which of such differences would be diagnostically useful—and to what diagnostic end. Moreover, many such identified differences might have no known consequences, i.e., knowledge of the difference would lack any practical or real-world value.

48 774 F. 3d at 763-764.
The Supreme Court—decades ago—squarely invalidated claims similarly lacking in any substantial utility in *Brenner v. Manson*, *supra*. The ineligible claims appear to be prototypically *Brenner*-like in character. Thus, the *In re BRCA1 & BRCA2* claims fit the pattern in *Myriad* and *Mayo*—more “bad” claims resulting more bad ineligibility law. Yet again, the claims found patent ineligible could have been readily invalidated on non-eligibility grounds, consistent with the redundancy hypothesis.

4. **ARIOSA v. SEQUENOM: ANOTHER PATENT WITH CLAIMS TOO BROAD TO BE VALID?**

No decision of the Federal Circuit in the post-*Alice* era is more notorious among proponents of a strong patent system than the *Ariosa v. Sequenom* holding. The claim of the Sequenom patent at issue in *Ariosa v. Sequenom* most cited as errantly held ineligible for patenting is claim 1:

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.

However, also at issue in the appeal was claim 21:

21. A method of performing a prenatal diagnosis, which method comprises the steps of:
   (i) providing a maternal blood sample;
   (ii) separating the sample into a cellular and non-cellular fraction;
   (iii) detecting the presence of nucleic acid of fetal origin in the non-cellular fraction according to the method of claim 1; and
   (iv) providing a diagnosis based on the presence and/or quantity and/or sequence of the fetal nucleic acid.

Claim 21 is a diagnostic claim that incorporates all the limitations of claim 1. If claim 21 is patent ineligible, it should likewise follow that claim 1—by incorporating patent-ineligible subject matter within its scope—should likewise be patent ineligible.

The key question, therefore, in addressing the issue of whether or not the Supreme Court’s “implicit exception” jurisprudence is merely duplicating grounds for invalidity of otherwise unpatentable claims, can best be focused on the issue of the validity of claim 21 on grounds other than patent eligibility. Self-evidently, if claim 21 is invalid on grounds such as

---

49 U.S. Patent 6,258,540.
50 Col. 21, lines 61-67 and col. 26, lines 4-14, ‘540 patent.
novelty, obviousness, or breadth of disclosure, it is impossible that claim 1—the independent claim from which claim 21 depends—could survive as valid on the same ground for invalidity.

In addressing claim 21’s § 112(a) validity, the claim appears to cover not only the very few diagnostic tests that Sequenom devised and disclosed in its patent specification (i.e., tests in which the diagnosis is based on the presence of non-cellular-origin paternal DNA in maternal blood), but all such diagnostic tests that might ever be devised. Thus, claim 21 raises the same commonly encountered sufficiency of disclosure issues that numerous biotechnology-related patents have faced: Given that Sequenom apparently seeks patent exclusivity over all possible diagnostic tests ever discovered based on the identification of non-cellular-origin paternal DNA in maternal blood, has the Sequenom patent specification both described and enabled all such technology—to an extent commensurate with the breadth of the claims?

On the § 112(a) “written description” front, does the specification’s description go beyond simply disclosing the function the critical elements the claimed method are to perform (or the result they are to achieve) and instead actually identify the structures or materials themselves to which the crucial claim elements are directed? On the enablement front, can the full scope of the claim be practiced with ordinary skill not requiring undue experimentation?

The most cogent answer to the above questions may be found most in the jurisprudence of the Supreme Court in its Halliburton decision. As in Halliburton, claim 21 is directed to a method with a number of discrete elements—individual limitations—none of which by itself is new, e.g., prenatal diagnoses are not new, maternal blood samples are not new, separating blood samples into cellular and non-cellular components is not new, and DNA of fetal origin is not new, whether of maternal or paternal origin. The claim, thus, is a combination of old elements. However, what is new—and brilliantly so on Sequenom’s part—is the combination of such individually old elements to yield the non-invasive fetal diagnostic tests theretofore unknown.

However, by far the most crucial element in the new combination of old elements is the identity of the non-cellular, paternal fetal DNA sequences that are used to make the particular diagnosis in a patient. The Supreme Court’s Halliburton holding specifically speaks to the sufficiency of the disclosure needed for such a crucial element. The necessary “written description” must extend to the structure (i.e., physical nature) of the DNA that determines what diagnostic conclusions might be drawn:

The language of the [Halliburton] claim thus describes this most crucial element in the “new” combination in terms of what it will do rather than in terms of its own physical characteristics or its arrangement in the new combination apparatus. We have held that a claim with such a description of a product is invalid… . We understand that the Circuit Court of Appeals held that the same rigid standards of description required for product claims is not

---

required for a combination patent embodying old elements only.

We have a different view.\textsuperscript{52}

Claim 21, because of its functional breadth, commits the original sin of \textit{Halliburton}. The last step of claim 21 (making “diagnosis based on the presence and/or quantity and/or sequence of the [paternally inherited] fetal nucleic acid”) identifies the DNA solely by its function—capability for providing some diagnosis—without identifying the condition to be diagnosed, much less the chemical structure (or absence thereof) that must be ascertained to permit the diagnosis to be made.

The decision in \textit{Halliburton} remains the definitive interpretation of § 112(a) except for claims that qualify for the claim construction limitation 35 U.S.C. § 112(f). For reasons detailed below, § 112(f) is inapplicable to claim 21; the claim is not set out as a “step for” claim of the type for which Congress negated \textit{Halliburton} invalidity in exchange for limiting infringement of the claim to the acts disclosed for performing the stated function in the claim—and equivalent acts.

If dependent claim 21 is too broad to meet the strictures under § 112(a) as interpreted by the Supreme Court in \textit{Halliburton}, then the yet-broader claim 1 from which it depends could scarcely be found valid under the same statutory standard. Independent claim 1 would necessarily have the fatal overbreadth defect, compounded by its yet-broader scope of protection.

The Federal Circuit found these statutorily unpatentable claims to be patent ineligible in a decision most frequently noted by the decision’s critics for its analytical emptiness. Given this criticism, it is worthwhile looking at the substantive criticisms that have been leveled against the court’s handling of the Sequenom claims.

Sequenom’s claim 1 contained only two steps. The first step required “amplifying” DNA. Amplification requires only taking an existing DNA sample and using the DNA compound itself as the template for making additional physical copies of the unamplified DNA itself. This chemical process step should have raised no issues of patent eligibility.

The second step requires detecting or identifying by some physical means certain DNA that might be found in the amplified sample. The claim contains no additional elements—nothing further needs to be done by an accused infringer to infringe the patent.

There are no Prometheus-like “wherein” clauses that suggest the need for mentally comparing—making some correlation to the natural environment. No law or product of nature is being preempted in manipulating and examining physical samples. The acts are to be performed in the physical world, by manipulation of physical objects. As such, the claim cannot be said to be directed merely to a natural or physical phenomenon.

In a like vein, there is nothing merely abstract about the physical acts that must be performed to infringe the claim. There are not an idea or concept. Rather, they constitute a

\textsuperscript{52} 329 U.S. at 8-9.
startlingly non-obvious method for finding paternally inherited DNA in a haystack that therefore had been thought to be wholly devoid of such DNA needles.

So, how could Sequenom’s claim 1 have been found ineligible for patenting? Exemplary of the deficiency often cited in the Federal Circuit’s analysis is its discussion of the manner in which the Federal Circuit held the claims were directed to a phenomenon of nature, i.e., naturally occurring subject matter:

It is undisputed that the existence of [cell-free fetal DNA] in maternal blood is a natural phenomenon. Sequenom does not contend that [the inventors] created or altered any of the genetic information encoded in the [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 [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.53

Examined at the level of abstractness at which the Federal Circuit examined the Sequenom claims to determine what they were “directed to,” a vast array of inventions would satisfy the “directed to” test. Such claims could then be patent eligible only if the “inventive concept” criterion of Mayo/Alice were satisfied. As formulated above, almost any claim taking the first part of the two-part test would be handed a passing grade.

As to the second part of the two-part test, the Federal Circuit’s reasoning has been repeatedly criticized as no less mystifying:

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 [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. … Thus, in this case, appending routine, conventional steps to a natural phenomenon, specified at a high level of generality, is not enough to supply an inventive concept. Where claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art.54

53 788 F.3d at 1376.
54 788 F.3d at 1377-78.
Notwithstanding the words in the Federal Circuit decision, the Sequenom claims neither begin nor end with a natural phenomenon—at least by any reckoning of what the words of the claim mean applied to the real world in which the Sequenom invention would be practiced. Amplifying DNA using polymerase chain reaction—PCR—may well be one of the greatest man-made inventions in all of human history—it is hardly a natural phenomenon. Similarly, detecting genetic material in a test tube is no more directed to a law of nature than detecting a fish at the end of the line on a fishing pole. Both are reference to fully human acts—not nature’s.

Hence, as in Mayo, Myriad, and In re BRCA1 & BRCA2, for a fourth time the courts have found claims that would have been unpatentable on non-eligibility patentability grounds to be patent ineligible. Again, this decision is in no way inconsistent with the validity of the redundancy hypothesis.

That said, the potential for incremental harm inherent in the two-part test is abundantly clear from the Sequenom decision. The two-part test has the apparent potential for broad applicability to any claimed invention—otherwise unpatentable or not. Thus, even though the Sequenom holding provides additional empirical support for the redundancy hypothesis—inventions properly found ineligible under Mayo/Alice would inevitably be found unpatentable on non-eligibility grounds—the looseness of the reasoning offered by the Federal Circuit suggests that the redundancy hypothesis, if false, may fail because of the immense variability that is inherent in the application of the two-part test.

5. **GENETIC TECHNOLOGIES: AN ENABLEMENT-DEFICIENT CLAIM FOUND INELIGIBLE?**

In *Genetic Technologies v. Merial* the Federal Circuit was confronted with a claim that—based upon prior precedents—was sufficiently conceptual in character that the successful application of the Mayo/Alice two-part test was inevitable and the finding of patent ineligibility almost assured given the breadth of the claim at issue. The prototype claim contained two steps:55

1. A method for detection of at least one coding region allele of a multi-allelic genetic locus comprising:
   a) amplifying genomic DNA with a primer pair that spans a non-coding region sequence, said primer pair defining a DNA sequence which is in genetic linkage with said genetic locus and contains a sufficient number of non-coding region sequence nucleotides to produce an amplified DNA sequence characteristic of said allele; and
   b) analyzing the amplified DNA sequence to detect the allele.

The key limitation in the claim is found in the phrase referencing a “DNA sequence which is in genetic linkage with said genetic locus,” with the “genetic locus” being the “site on a

---

55 Claim 1 of U.S. Patent 5,612,179.
chromosome occupied by a particular gene." The DNA sequence that is in “genetic linkage” references the “linkage” between sequences within the gene to sequences not part of the gene, which may be in non-coding regions on the same or even a different chromosome. Such “linked” sequences were known in the prior art.

Claim 1, thus, purports to set out a method that can be used to find “alleles”—variations in the DNA sequence within a particular gene—by looking not at the DNA sequence of the gene itself, but at a DNA sequence elsewhere in the genome that is “in genetic linkage.” In order to practice the invention as broadly as claimed, a person skilled in the art would need to understand what the linkages were—and were not—throughout a genome. Indeed, the claim is crafted broadly enough to encompass a genome of any organism in the universe.

This type of claim raises a classic enablement issue, often successfully asserted as an invalidity defense in biotechnology litigation where broad claims of this type are presented. Had the issue of “enablement” under 35 U.S.C. § 112(a) been recognized the Federal Circuit—given it is a question of law—it is likely that the mere breadth of the claim might have led the court to invalidate the claim under § 112(a)—possibly sua sponte!

Indeed, in Genentech, Inc., v. Novo Nordisk, A/S, Novo Nordisk of North America, Inc., 108 F.3d 1361 (Fed. Cir. 1997), the Federal Circuit addressed the “enablement” issue in an appeal brought by the patent owner after the denial of the patent owner’s motion for a preliminary injunction. In that appeal, the Federal Circuit not only disappointed the patent owner by sustaining the denial of its preliminary injunction motion, but then took the further step of granting relief not sought by the accused infringer during the summary judgment appeal—the court summarily invalidated the patent for non-enablement.

The Genentech court summarized the collective import of much of the jurisprudence relating to the issue of enablement:

[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the

56 818 F.3d 1371.
57 "In the 1980s, Dr. Malcolm J. Simons, the named inventor …, discovered an interesting feature of genomic DNA. Dr. Simons discovered that certain DNA sequences in coding regions (exons) of certain genes are correlated with non-coding regions (introns) within the same gene, non-coding regions in different genes, or non-coding regions of the genome that are not part of any gene. … Dr. Simons found that the correlated coding and non-coding regions tend to be inherited together, with only rare shuffling. In other words, the regions are in "linkage disequilibrium," meaning that the coding and noncoding regions appear ‘linked’ together in individuals' genomes more often than probability would dictate. … ('[L]inkage disequilibrium [is a] condition in which certain alleles at two linked loci are non-randomly associated with each other.’). The correlated coding and non-coding regions may be linked even though the two sequences are located far apart from one another on the chromosome.” 818 F.3d 1372.
58 In this appeal the court was reviewing a decision of the trial court granting Genentech a preliminary injunction, based on “likelihood of success on the merits” of sustaining validity of its patent claim. Novo Nordisk countered that the Genentech patent claim was invalid for—among other reasons—non-enablement, negating any likelihood of success in sustaining validity. The Federal Circuit, as described infra, vacated the preliminary injunction and held as a matter of law that the Genentech claim was non-enabled.
59 108 F.3d 1365.
claimed invention without ‘undue experimentation.’” In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993); see also Amgen Inc. v. Chugai Pharmaceuticals. Co., 927 F.2d 1200, 1212 (Fed. Cir. 1991); In re Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970) (“[T]he 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.”). Whether making and using the invention would have required undue experimentation, and thus whether the disclosure is enabling, is a legal conclusion based upon several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37 (Fed. Cir. 1988).

The application of the factors set out in Wands,60 given the 1989 priority date for the claimed invention in Genetic Technologies and the more nascent nature of the genetic engineering knowledge then existing, suggests that the Federal Circuit, had the court focused on enablement as it did sua sponte in denying Genentech’s preliminary injunction and then summarily invalidating its claims, would have held that claim 1 could not have survived as valid.

Given the likely judicial finding of non-eligibility unpatentability, the pattern of the prior ineligibility holdings examined above continues. Confronted with broad claims that the courts have found to be patent ineligible, the patent owner would likely have found such broad claims susceptible to a successful attack on adequacy of disclosure grounds. Again, the redundancy hypothesis finds further support.

6. CELLZDIRECT: THE TWO-PART TEST RESULTS IN A PATENT CLAIM FOUND ELIGIBLE!

The key claim at issue in the CellzDirect appeal61 reads as follows:

1. A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising:
   (A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from nonviable hepatocytes,
   (B) recovering the separated viable hepatocytes, and
   (C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time, wherein the hepatocytes are not plated between

---

60 The “Wands factors” used to determine if undue experimentation would be required to practice the claimed invention, thereby rendering it non-enabled, are commonly cited as: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. 858 F.2d at 737.

the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.

In examining patent eligibility of the above claim under the Mayo/Alice two-part test, the Federal Circuit was asked to overrule a district court’s summary judgment determination that the claimed invention was patent ineligible, even though a fair reading of the claim—or even an effort to construe the claim broadly—makes it difficult to discern (as in Sequenom above) a basis on which the two-part test could reasonably result in an ineligibility holding.

Fortunately for the patentee, the Federal Circuit had no difficulty nixing the lower court’s finding that the claims were directed to a patent-ineligible concept, distinguishing prior judicial holdings in cases where the claims were so directed:

The claims in this case are immediately distinguishable from those we have found patent ineligible in cases since Mayo and Alice. In recent cases, we found claims “directed to” a patent-ineligible concept when they amounted to nothing more than observing or identifying the ineligible concept itself. For example, in Genetic Technologies, the claim recited methods for detecting a coding region of DNA based on its relationship to noncoding regions. … Because the relationship between coding and non-coding sequences was a law of nature, the claim amounted to nothing other than identifying “information about a patient's natural genetic makeup.” … Likewise in Ariosa, the claims recited methods for detecting paternally inherited cffDNA in the blood or serum of a pregnant female. … The existence and location of cffDNA is a natural phenomenon; identifying its presence was merely claiming the natural phenomena itself. … And in In re BRCA, the claims recited methods for screening human germline for an altered BRCA1 gene by comparing the target DNA sequence with wild-type sequence. … But comparing two sequences to detect alterations is a patent-ineligible “abstract mental process.” … Although the claims in each of these cases employed method steps, the end result of the process, the essence of the whole, was a patent-ineligible concept.

Indeed, the claims in CellzDirect appear to be “immediately distinguishable” from each of the claims analyzed above that were found to be directed to an abstract idea or other concept. The process steps of the CellzDirect claims involved are all highly physical in character. They are physical steps that might be practiced industrially.

---

The fact that the claims on appeal were directed to *frozen hepatocytes*, rather than, say, *frozen Swanson Chicken Dinners*\(^6^3\) should have been of no consequence to either the Federal Circuit or the lower court. The rather remarkable decision of the trial court finding these hepatocyte-related claims ineligible may suggest that *Mayo/Alice* test imposes a special burden on biomedical related inventions whenever the subject matter being claimed appears more “abstract” than, say, a frozen chicken dinner.

It is doubtful, for example that, if the claims had been directed to a process for refreezing frozen chicken dinners (such that they could be thawed and frozen multiple times with 70% of the meals surviving the second thaw and freeze), the trial court would have seen the claims as being directed to a “concept” rather than to patent-eligible tasty meals.

Reading the claims and the specification in light of the reported decision on appeal, it appears that nothing in the claims suggests a breadth that would have necessarily led to a finding of invalidity on non-eligibility, patent-validity grounds. However, the district court’s decision again exposes the uncertainty inherent whenever the two-part test is memorialized in a decision of a court.

The history of this litigation, while it does nothing to negate the redundancy hypothesis, again suggests that if the redundancy hypothesis were to fail, that failure would likely come because the two-part test overreachesc—by invalidating claims where there would be no discernable policy rationale for asserting the patent system was being abused by a clever patent draftsman seeking protection over a law/product of nature, natural/physical phenomenon, or abstract idea or other concept.

7. **Cleveland Clinic: Yet Other Prometheus-Like Claims Invalidated?**

In *Cleveland Clinic*, the Federal Circuit found ineligible claims in three different patents that, in each case, were similar to those of Prometheus in the *Mayo* decision. Typical of the problematic claims found in one of the Cleveland Clinic patents was the following:\(^6^4\)

11. A method of assessing a test subject’s risk of having atherosclerotic cardiovascular disease, comprising

- comparing levels of myeloperoxidase in a bodily sample from the test subject with levels of myeloperoxidase in comparable bodily samples from control subjects diagnosed as not having the disease,

  said bodily sample being blood, serum, plasma, blood leukocytes selected from the group consisting of neutrophils, monocytes, sub-populations of neutrophils, and sub-populations of monocytes, or any combination thereof;

- *wherein the levels of myeloperoxidase in the bodily from the test subject relative to the levels of myeloperoxidase in the*

\(^6^3\) Such still exist. See [http://www.swansonmeals.ca/dinners/fried_chicken.asp](http://www.swansonmeals.ca/dinners/fried_chicken.asp).

\(^6^4\) Claim 11 of U.S. Patent 7,223,552. The text of the claim above corrects two typographical errors in the patent as printed. Emphasis added.
comparable bodily samples from control subjects is indicative of the extent of the test subject's risk of having atherosclerotic cardiovascular disease.

The terminal “wherein” clause of claim 11, properly construed, is merely an observation, i.e., a do-nothing clause. It should in no way be interpreted to limit the claim. The claim scope would be equally infringed with or without any activity associated with this terminal clause.

With this in mind, claim 11 could be rewritten into an equivalent form by relocating the “wherein” clause into the preamble of the claim—and otherwise separating the stated act set out in the single step of the claim from the verbiage in the claim defining the subject’s “bodily samples.” Doing so produces a simplified version of claim 1 having an identical scope that would read as follows:

11. A method of assessing a the extent of a test subject’s risk of having atherosclerotic cardiovascular disease, based upon the levels of myeloperoxidase in a sample of said test subject’s blood, serum, plasma, blood leukocytes (selected from the group consisting of neutrophils, monocytes, sub-populations of neutrophils, and sub-populations of monocytes), or any combination thereof, relative to the levels of myeloperoxidase in the comparable bodily samples from control subjects diagnosed as not having the disease comprising

comparing said levels of myeloperoxidase in said test subject with said levels of myeloperoxidase from said control subjects.

Redrafting claim 11 in the above manner confirms that the claim is properly construed as a one-step process. More specifically, the redrafted claim 11 can be seen as such a broadly drafted claim that the one step in the claim could readily be performed entirely in the human mind.

To infringe claim 11 requires nothing more than comparing two values. It does not require drawing any conclusion from the comparison. It presumably requires nothing more than making a purely mental note that one of the two values referenced in the claim is larger than the other or that the values are identical—or substantially so. Moreover, the claim itself does not even suggest what conclusion (diagnosis) might be appropriate if one value is greater than the other. Are higher “control values” indicative of disease—or are lower “control values” indicative of disease—or are both higher or lower “control values indicative of disease—relative to the subject’s test value?65

65 The Federal Circuit’s opinion references other claims of the ‘552 patent a similar ilk. The pertinent aspects of claim 14 were directed to the one-step method able to be performed exclusively through human thought, i.e., “A method of assessing a test subject's risk of developing a complication of atherosclerotic cardiovascular disease comprising: determining levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or both
The Federal Circuit found these one-step Cleveland Clinic claims to be directed to a law of nature and devoid of any “inventive concept,” by relying heavily on its Ariosa v. Sequenom holding.

The court then applied this same analysis to a two-step process claim in another Cleveland Clinic patent before the court. The ineligible two-step process claim contained both a determining step and a comparing step, with only the second of these two steps being set out broadly enough so as to be capable of performance mentally.

5. A method of determining whether a patient who presents with chest pain is at risk of requiring medical intervention to prevent an adverse cardiac event within the next six months comprising:

- determining the level of risk predictor in a bodily sample from the subject,
- wherein said risk predictor is myeloperoxidase activity, myeloperoxidase mass, a myeloperoxidase (MPO)-generated oxidation product or any combination thereof,
- wherein said bodily sample is blood, serum, plasma or urine,

wherein said myeloperoxidase-generated oxidation product is nitrotyrosine or a myeloperoxidase-generated lipid peroxidation product, and

- comparing the level of said risk predictor in the bodily sample of the patient to the level of said risk predictor in comparable samples obtained from a control population,
- wherein a subject whose bodily sample contains elevated levels of said risk predictor as compared to the control value is at risk of requiring medical intervention to prevent an adverse cardiac event within 6 months of presenting with chest pain.

in a bodily sample of the test subject. Claim 21 of a second patent, U.S. Patent 7,459,286, produces the same result through a “characterizing” step: “A method of assessing the risk of requiring medical intervention in a patient who is presenting with chest pain, comprising characterizing the levels of myeloperoxidase activity, myeloperoxidase mass, or both, respectively in the bodily sample from the human patient….” 859 F.3d at 1356-7.

66 “[T]he testing patents purport to detect MPO and other MPO-related products, which are naturally occurring in bodily samples. The method then employs the natural relationship between those MPO values and predetermined or control values to predict a patient's risk of developing or having cardiovascular disease. Thus, just like Ariosa, the method starts and ends with naturally occurring phenomena with no meaningful non-routine steps in between—the presence of MPO in a bodily sample is correlated to its relationship to cardiovascular disease. The claims are therefore directed to a natural law.” 859 F.3d at 1361.

67 “The claims, whether considered limitation-by-limitation or as a whole, do not sufficiently transform the natural existence of MPO in a bodily sample and its correlation to cardiovascular risk into a patentable invention. The process steps here merely tell those ‘interested in the subject about the correlations that the researchers discovered.’” 859 F.3d at 1362.

68 Claim 5 of U.S. Patent 8,349,581, 859 F.3d at 1357.

69 The “wherein” clauses other than the terminal “wherein” clause in the Cleveland Clinic two-step claim self-evidently imposes claim limitations that must be met for the claims to be infringed.
If the non-limiting, terminal “wherein clause” is jettisoned from claim 5 above, the skeletal essence of what remains is:

A method of determining whether a patient … is at risk … comprising: [1] determining the level of [a] risk predictor … from the subject … and [2] comparing the level of said risk predictor … to the level … from a control… .”

The apparent intent of this generalized form of claim is to assure that both positive and negative diagnostic outcomes are covered by the claim, i.e., would infringe the claim. To compose a claim that has such a breadth requires eschewing any limitations that would preclude the claim from being entirely agnostic about the actual diagnosis made for an individual patient. In this sense, as the Federal Circuit noted in Judge Reyna’s opinion, what results can be characterized as a testing patent rather than a diagnostic patent.70

Had Cleveland Clinic presented claims directed to a specific diagnostic method in which the patient on whom the test was performed was diagnosed, not simply tested, it is possible that the patent ineligibility would have been negated by the presence of additional steps needed to effect such a limitation. In a true diagnostic claim, for example, it ought to be possible to avoid the use of a step crafted so broadly as to be capable of being performed in the human mind, i.e., the “mental step,” as well as to avoid the “do-nothing,” observational language in the non-limiting “wherein” clauses.

A true diagnostic claim set, with only physical (non-mental) steps requiring that a specific determination (i.e., diagnosis) could be remarkably simple to craft:

1. A method of diagnosing that a patient is at a risk for [Condition X] comprising:
   determining that said patient has an elevated level of [a risk predictor for Condition X] relative to the level of said risk predictor from a control population.”

2. A method according to claim 1 further comprising documenting the determination of said elevated level.

The above claims, through a proper application of Mayo/Alice, should be found patent eligible—not directed to a law/product of nature, natural/physical phenomenon, or other abstract idea or concept. Eligibility under the Mayo/Alice two-part test should be assured because of what the claim should be found to be directed to: diagnosing a patient by determining if a specific result was obtained from administering a specific test.

The lessons to be drawn from Cleveland Clinic may be similar to lessons from Mayo v. Prometheus. First off, better claims (such as the above diagnostic method claims) may well

70 “Here, the testing patents here do not extend their discovery that MPO correlates to cardiovascular risk to a patentable method. They require only conventional MPO detection methods and compare those values to predetermined or control values derived from conventional statistical methods.” 859 F.3d 1362.
produce a better result on patent eligibility than claims to mere testing. Second, as in Mayo, claims on their face may appear conceptual in nature if drafted so broadly that they have steps that can be performed entirely in the human mind.

The invalidated claims of both Mayo and Cleveland Clinic fell into these categories. It appears, thus, that testing claims—particularly those that contain steps set out broadly enough such that they can be performed mentally—can be expected to be far more problematic than true diagnostic claims under the two-part test.\(^{71}\)

The Cleveland Clinic claims here raise an interesting legal question relevant to the validity of the redundancy hypothesis: Should process claims written broadly enough to encompass a step capable of being performed mentally be held as a matter of law to lack enablement under § 112(a)? The Federal Circuit appears to have (indirectly at least) answered this issue in the negative.

\(^{71}\) Another recently invalidated set of diagnostic method claims can be found in Athena Diagnostics, Inc. v. Mayo Collaborative Services, et al, Civil Action No. 15-cv-40075-IT (D. MA, August 4, 2017). The court invalidated claims of U.S. Patent No. 7,267,820 as patent ineligible under a motion to dismiss under Rule 12(b)(6). However, the patent ineligible claims appear to be otherwise unpatentable as lacking in the required “written description,” if not enablement, under § 112(a). Ineligible claim 1 of the patent read:

1. A method for diagnosing neurotransmission or developmental disorders related to muscle specific tyrosine kinase (MuSK) in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of muscle specific tyrosine kinase (MuSK).

The claim specifies neither the antibody nor the epitope nor the manner of antibody detection. Moreover, the sole “detecting” step is not disease- or diagnostic-limited—it simply requires identification of the autoantibodies, without more. Dependent claim 2 is substantially more limited in scope:

2. A method according to claim 1 wherein said method comprises the steps of:
   a) contacting said bodily fluid with muscle specific tyrosine kinase (MuSK) or an antigenic determinant thereof; and
   b) detecting any antibody-antigen complexes formed between said receptor tyrosine kinase or an antigenic fragment thereof and antibodies present in said bodily fluid, wherein the presence of said complexes is indicative of said mammal suffering from said neurotransmission or development disorders. [Emphasis added.]

Nonetheless, the two steps of claim 2 still broadly—and functionally—recite use of a reagent that is defined only as the antigen for the antibody to be detected. As such, a claim of such breadth as to extend to any functionally defined antigen likely would not survive a § 112(a) “written description” challenge as recent Federal Circuit jurisprudence has declined to offer antibody claims a “free ride” under the written description jurisprudence, \textit{i.e.}, Amgen v. Sanofi, App. No. 2017-1480 (October 5, 2017). Claim 3, which further limits claim 2, \textit{i.e.}, “A method according to Claim 2 wherein said antibody-antigen complex is detected using an anti-IgG antibody tagged or labeled with a reporter molecule.”), appears likely to fare no better under a § 112(a) validity analysis. The trial court’s decision here is significant because it demonstrates the efficiency with which the courts are able to dispose of patents under the Mayo/Alice two-part test. In this instance, the patent did not survive even to a summary judgment ruling—the claim was simply dismissed on the pleadings.
The dicta in *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1373 (Fed. Cir. 2011) would suggest entirely mental processes are ineligible, but partially mental processes may be patent eligible:

Methods which can be performed entirely in the human mind are unpatentable not because there is anything wrong with claiming mental method steps as part of a process containing non-mental steps, but rather because...methods which can be performed *entirely* in the human mind are the types of methods that embody the “basic tools of scientific and technological work.” (Emphasis in original)).

If the Federal Circuit’s observation is to be accepted, then a single-step process claim containing a single *comparing* would be patent ineligible because it has been crafted so broadly that it “can be performed entirely in the human mind.” In contrast, the above dicta seems to suggest that a two-step claim that further required, in a second step, nothing more than *announcing* the result of a mental comparison under the mental step could qualify as patent eligible.

However, if claims limited to a single “mental step” are categorically patent ineligible, then coupling such ineligible subject matter with a conventional, trivial second step would appear no less problematic for the reason indicated by the Federal Circuit, *i.e.*, no less capable of embodying the “basic tools of scientific and technological work.” Thus, if this Federal Circuit dicta is to be taken seriously that entirely mental processes are patent ineligible, it must be the case that partially mental processes can raise exactly the same policy issues to exactly the same degree as entirely mental processes. In other words, if wholly mental processes cannot be validly patented, then the very policy considerations cited by the Federal Circuit would indicate that partially mental processes may share the same patentability defect.

Indeed, the patent ineligibility of partially mental processes is apparent from decisions such in *Mayo* and *Cleveland Clinic*—one by the Supreme Court and another by the Federal Circuit. In both cases, the addition of a single mental step transformed what otherwise would have been a clearly patent eligible process into an ineligible one. Whatever the rationale cited in these decisions for the holding of ineligibility, the holding must be attributed to the presence of a single mental step in the ineligible claims.

If one takes away from *Mayo* and *Cleveland Clinic* the lesson that process claims containing one or more steps expressed broadly enough to be capable of being performed mentally are either highly problematic—or even fatal—to a finding of patent eligibility, then the next question that must be addressed is whether or not such a ground for unpatentability is merely redundant in light of the statutory patentability grounds for invalidating such claims. Put another way, are there non-eligibility patentability grounds on which process claims crafted broadly enough to encompass one or more steps capable of being performed mentally should be routinely found invalid?
If there were such a non-eligibility ground on which such partially mental process claims should be found to be unpatentable, it would almost certainly be for lack of sufficient enablement, *i.e.*, enablement that is commensurate with the scope of the claim, as required under § 112(a). This is an issue where—once again—the Supreme Court’s sufficiency-of-disclosure holding in *Halliburton* may be of decisive relevance.

A process step written at the level of generality such that the step is capable of being performed mentally, by its very nature, sets out no act to be performed; the step may be carried out merely through human thought. The lack of a real-world “act” is clear since (as yet) there is no way to determine what thoughts are taking place in a human mind at any given time—since (as yet) there is no way of knowing what another human being is really thinking. As a consequence, there is no ready way of enforcing an injunction against infringing a patented human thought.

If the Supreme Court’s *Halliburton* decision applies to mental process steps, then the unpatentability arising from decisions such as *Mayo* and *Cleveland Clinic* could be alternatively understood as nothing more than an aspect of unpatentability based on overbreadth of claiming under § 112(a)—claims with critical steps expressed in terms broadly enough to cover performance of the step through human thought. In such a case—once again—the *Cleveland Clinic* ineligibility holding would be just another example of the apparent redundancy of the *Mayo/Alice* two-part test applied to an otherwise unpatentable claim.

Thus, if the partially mental processes that have given rise to patent ineligibility holdings can alternatively be understood to create the *Halliburton* defect of overly broad claiming, such an understanding would supply a missing analytical link further validating the redundancy hypothesis.

**Lessons Learned: Biomedical Patenting from Reported Mayo/Alice Court Decisions**

Each of the above decisions, read in the context offered by this paper, offers support for the redundancy hypothesis. It would appear that, in the biomedical field at least, patent-eligibility challenges are made—and typically succeed—almost exclusivity against claimed inventions that otherwise would face serious challenges to their validity. The eligibility-deficient claimed inventions typically are drafted in a problematic manner such that their unpatentability may be compelled on one or more non-eligibility patentability grounds.

This lesson learned can be restated (without too much hyperbole) in an even more provocative manner: *In the biomedical field, patent eligibility challenges can succeed, but—to date at least—only against claimed inventions that should inevitably be found unpatentable if the non-eligibility requirements for patentability were fully understood and rigorously applied against the ineligible claims.*

Assuming the potential validity of the redundancy hypothesis has been adequately established (as it has been above for biomedical inventions), is there any justification whatsoever for the continuation of the “implicit exception” jurisprudence—again, at least as it is applied to
biomedical inventions? If not, then the above analysis should readily support abrogation of the “implicit exception” jurisprudence and its two-part test for implementation.

As briefly noted above, despite all of the shortcomings of the “implicit exception” jurisprudence, it could it have the redeeming virtue of operational efficiency—given its amenability to being used as a summary judgment/Rule 12(b)(6) tool early-on in patent litigation. Is this enough to justify keeping the two-part test alive?

Part of the consideration of the virtue-of-expediency issue requires placing the present discussion in a more international context. The two-part test routinely holds inventions ineligible for patenting in the United States for which eligibility for patenting is assured under foreign patent law across the globe. As a consequence, it is a precedent that, even if not pernicious here, could, in more anti-patent jurisdictions abroad, be used promiscuously in a non-redundant, incremental manner to destroy all manner of eminently patentable inventions—at significant risk to the global competitiveness of U.S. innovators. The district court decision in CellzDirect is emblematic of the potential of mischief that the two-part test can work. In CellzDirect, but for the Federal Circuit’s reversal, categorically patent-eligible subject matter would have been errantly found ineligible.

Another aspect of the two-part test that calls out for more focused consideration is its domestic potential for ongoing judicial metamorphosis. Even if the above data on ineligibility and non-eligibility unpatentability demonstrates a mere redundancy of the two-part test today, the amorphousness of the two-part test creates a credible prospect that this test will ultimately take on a more vigorous judicial life of its own. The test is entirely disconnected from the patent statute—indeed, it is an exception to the statute. As such, with no statutory underpinnings and no statutory constraints, the test could come to apply much more broadly.

In a worst case scenario, the two-part test might someday become a marauding ground for unpatentability of inventions that otherwise have neither any rational patent policy nor any statutorily-derived justification for holding such inventions unpatentable. When the courts operate in a manner untied to any statutory standard, imposing entirely judge made doctrines of patent invalidity, such unfortunate outcomes are not unknown.72

72 The doctrine of “obviousness-type” double patenting is the “poster child” for this type of judicial excess in invalidating patents without any rational policy ground on which to invalidate a patent that meets each of the applicable statutory limitations on the ability to enforce a patent. In the case of “obviousness-type” double patenting, courts have been criticized for finding the respective claimed inventions of two patents to be patentably indistinct notwithstanding the patent statute itself dictates that the respective inventions are non-obviously distinct and by holding that the claim of one patent is an unjustified timewise extension of the patent life of a second claim of a second patent notwithstanding that the limited period of additional patent life had been explicitly justified by Congress under the Uruguay Round Agreements Act of 1994 Uruguay Round Agreements Act, Pub. L. 103–465, 108 Stat. 4809 (1994).and the American Inventors Protection Act of 1999, Pub. L. 107-273 116 Stat. 1757-1922 (2002). See H.R. 9, 114th Congress, House Report 114-235 (July 29, 2015), https://www.congress.gov/114/crpt/hrpt235/CRPT-114hrpt235.pdf, at p. 50 (footnotes109 and 111), citing Eli Lilly and Co. v. Barr Labs., 251 F.3d 955 (Fed. Cir. 2001), In re Hubbell, 709 F.3d 1140 (Fed. Cir. 2013), and Gilead Sciences, Inc. v. Natco Pharma Ltd., 753 F. 3d 1208 (Fed. Cir. 2014).
A final consideration that provides a counterweight to the supposed “expediency” virtue of the two-part test lies in the offsetting merits that might be built into the jurisprudence that would replace the test. Legislation abrogating the two-part test could offer substitute and superior expediencies for eliminating bad claims.

Indeed, any legislative effort at removing the bad eligibility law—at least any viable political effort to do so—may require a substitute judicial means for addressing such bad claims with an equal or greater procedural expediency as the two-part test. For example, in the courts, the policies underlying the judicially imposed, non-statutory limitations on patent eligibility under the two-part test appear to be at best difficult to distinguish from the policies that the courts have cited in limiting patent claims based upon an insufficient disclosure. The Supreme Court in both O’Reilly v. Morse, 56 U.S. 62 (1854) and Halliburton Oil Well Cementing Co. v. Walker, supra, railed against issuing patents with claims set out in broad and conceptual terms.

Indeed, the crafting of § 112(f) under the 1952 Patent Act was specifically designed to address such claims and—when applicable—avoid the possibility that a valid patent claim could be directed to a concept or otherwise be preemptive of all means to a stated end. As noted above, for claims setting forth an invention in broad, functional terms, they can be reined in under § 112(f) to cover just the embodiments that the inventor disclosed in the patent for performing the function.

A legislated substitute for an abrogated “implicit exception” and its two-part test could, thus, have a similar claim-limiting effect for all overly broad claims that would otherwise have failed both on sufficiency of disclosure grounds under § 112(a) and the two-part test implementing the “implicit exception.” If this were possible, it would be the ultimate expedient—a statutory self-correction for overly broad claims that would limit an overly broad claim scope to a valid, sustainable scope of protection.

In sum, therefore, given that the decisions of the courts implementing the Mayo/Alice two-part raise enough concerns—including concerns evident in the red-flag decision in Sequenom and the reversed trial court decision in CellzDirect—Congress would be justified in giving serious consideration to a patent system course correction via legislation. After the failure of the Supreme Court to reconsider its Mayo/Alice analytical debacle in Sequenom, the prospect for a satisfactory judicial—rather than legislative—remediation for biomedical-related patents would appear to be more a distant dream rather than option for a near-term nirvana.

Such reform legislation could have multiple goals. The prime and obvious goal would be the replacement of the “implicit exception” jurisprudence with workable and explicit patent-limiting provisions that bar patents for any law/product of nature, natural/physical phenomenon, or abstract idea or other concept. No entity, no matter how patent loving, has suggested that patent protection should be available for mere concepts.

A further goal could be enacting new provisions in the patent law to more thoroughly (or at least more clearly) address by statute the issues that arise when patents contain broad and conceptual claims. The objective of such new statutory rules could be to assure that patent eligibility limitations are not overused to deny such claims, but—when claims appear excessive
in scope—they can be summarily denied or invalidated. As to the goal of expedient invalidation of “bad claims,” such a goal might be accomplished by doing nothing more than extending (or perfecting) the efforts under the 1952 Patent Act to address the \textit{Halliburton} decision of the Supreme Court, \textit{i.e.}, by specifying as Congress did in 1952 by enacting 35 U.S.C. § 112(f) that when claims are written in terms merely functional terms that their scope may be limited to the embodied subject matter the patent specification has specifically disclosed.

Where might the above analysis and conclusions lead legislative efforts over the decade ahead? As noted above, over the past several years, multiple efforts have been undertaken to define a legislated alternative to the \textit{Alice/Mayo} two-part test? The remainder of this paper is devoted to the task of defining a possible \textit{union} of such efforts—\textit{composing, out of many, one.}

\textbf{The Path Forward – Stitching Four Different Solutions into a Single Statutory Tapestry}

Because the Supreme Court decisions imposing a two-part test reflect a judge-made standard that stands apart from the statutory requirements for patentability (\textit{i.e.}, the court decisions are a judicially imposed “implicit exception” that is not dictated by the statute itself), the jurisprudence is amenable to being superseded through a full codification of the law of patent eligibility. Congress enacted just such a superseding codification in 1952, which mooted the judge-made “invention” requirement through 35 U.S.C. § 103’s statutory non-obviousness requirement.\footnote{In \textit{Hotchkiss v. Greenwood}, 52 U.S. 248, 267 (1851), the Court held that the patent laws contained an implicit requirement that valid patent claims must be sufficiently inventive, in addition to meeting the then-existing statutory requirements. In enacting § 103 as part of the 1952 Patent Act, Congress superseded this implicit requirement with an explicit statutory requirement for non-obviousness; a valid patent cannot be granted if “the claimed invention as a whole would have been obvious.”}

The ABA IPL Section,\footnote{The Section of Intellectual Property Law of the American Bar Association. \url{https://www.americanbar.org/groups/intellectual_property_law.html}.} IPO,\footnote{Intellection Property Owners Association. \url{https://www.iipo.org/}.} AIPLA,\footnote{American Intellectual Property Law Association. \url{https://www.aipla.org}.} and a group of 18 Banbury Center Conference patent experts\footnote{Banbury Conference Center, Cold Springs Harbor Laboratory, NY. \url{https://www.cshl.edu/education/banbury/meeting-reports/}.} have recently proposed such a § 103-like superseding codification that would add new statutory limitations on patent eligibility, to be placed in 35 U.S.C. § 101. Under such proposals, the Supreme Court’s two-part test for determining the applicability of the “implicit exception” to patent eligibility would disappear and the new statutory limitations on the availability of valid patents would take their place. The ABA IPL Section has proposed a preemption-based bar to patent eligibility.\footnote{On March 7, 2017, the Council of the ABA IPL Section adopted the following resolution (emphasis supplied): \begin{center} RESOLVED, that the American Bar Association Section of Intellectual Property Law supports, in principle, amendment of 35 U.S.C. § 101 to clarify that useful inventions as defined by each and every limitation of the claims of a patent satisfy the patent eligibility requirements of section 101 so long as the claims do not preempt the use by others of all practical applications of laws of nature, natural phenomena or abstract ideas, and to clarify that the determination}
issue of whether preemptive claims would be patent ineligible and instead proposed that claims lacking in “human activity” or claims in which only “human thought” was required to carry out the claimed invention should be patent ineligible. The AIPLA eventually produced a resolution supporting an approach similar to the IPO proposal, but with some notable differences. Finally the proposal by the patent experts from the Banbury Center Conference

FURTHER RESOLVED, the ABA-IPL Section supports, in principle, replacing in its entirety the current statutory language of 35 U.S.C. § 101 with language substantively consistent with the following:


(a) ELIGIBLE SUBJECT MATTER.—Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, shall be entitled to obtain a patent on such invention or discovery, absent a finding that one or more conditions or requirements under this title have not been met.

(b) EXCEPTION.—A claim for a useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may be denied eligibility under this section 101 on the ground that the scope of the exclusive rights under such a claim would preempt the use by others of all practical applications of a law of nature, natural phenomenon, or abstract idea. Patent eligibility under this section shall not be negated when a practical application of a law of nature, natural phenomenon, or abstract idea is the subject matter of the claims upon consideration of those claims as a whole, whereby each and every limitation of the claims shall be fully considered and none ignored. Eligibility under this section 101 shall not be negated based on considerations of patentability as defined in sections 102, 103 and 112, including whether the claims in whole or in part define an inventive concept.”

On March 27, 2017, the ABA IPL Section resolution was transmitted to Under Secretary Michelle Lee. See http://patentdocs.typepad.com/files/letter-5.pdf.

79 The Intellectual Property Owners Association proposed to limit patentability under an amended 35 U.S.C. § 101, adopting the following resolution for doing so (emphasis added):

RESOLVED, that IPO supports legislation to amend 35 U.S.C. § 101 as follows:

(a) ELIGIBLE SUBJECT MATTER—Whoever invents or discovers, and claims as an invention, any useful process, machine, manufacture, composition of matter, or any useful improvement thereto, shall be entitled to a patent for a claimed invention thereof, subject only to the exceptions, conditions, and requirements set forth in this Title.

(b) SOLE EXCEPTION TO SUBJECT MATTER ELIGIBILITY—A claimed invention is ineligible under subsection (a) if and only if the claimed invention as a whole, as understood by a person having ordinary skill in the art to which the claimed invention pertains, exists in nature independently of and prior to any human activity, or exists solely in the human mind.

(c) SOLE ELIGIBILITY STANDARD—The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard as to the requirements or conditions of sections 102, 103, and 112 of this Title, the manner in which the claimed invention was made or discovered, or the claimed invention’s inventive concept.


80 Because the AIPLA proposal can be considered—at least to some extent—an alter ego of the IPO resolution, it is not addressed in detail herein. The text of the AIPLA effort can be found at:
argued that patent eligibility should be constrained under § 101 only to the extent that a claimed invention failed to contribute to a field of technology.81

The four proposals from these four entities do not dispute the fundamental premise underlying Supreme Court jurisprudence, namely that valid patent protection should not exist to protect a law or product of nature, a natural or physical phenomenon, or an abstract idea or concept. However, in the same manner that Congress replaced the judge-made requirement for “invention” in 1952 with a statutory non-obviousness requirement, the position taken under each of the four proposals is that the Supreme Court’s Mayo-Alice two-part test must be replaced with a § 101-based eligibility limitation as outlined above, leaving no room for an implicit exception.

Since each of the four proposals would make different substantive changes to the patent statute, they stand as a potential obstacle, not an encouragement, to congressional action. If Congress were to ask the patent community today if there were a single legislative proposal that could be advanced as representing common ground—on which Congress could credibly begin a legislative process—the answer would be negative. Self-evidently, for a legislative campaign to move forward to enactment of a new law, these four approaches cannot forever remain as competing alternatives for Congress to consider.


81 See https://www.uspto.gov/sites/default/files/documents/Updated%20Banbury%20Statement.pdf. The Banbury Center Conference proposal was endorsed by a group of 18 IP professionals who attended a November 9-11, 2016 conference devoted to subject matter eligibility for patenting. The proposal that emerged from that conference concluded that the following measures should be taken to address issues of subject matter eligibility for patenting (emphasis in original):

1. Clarify that patent protection shall be available for inventions in all fields of technology and better conform U.S. patent law with internationally accepted norms of patentability. To this end, a number of participants recommended that Congress enact a substitute requirement limiting patent eligibility to technological inventions, i.e., inventions contributing to the technological arts. Such a measure would codify the standard set out in the concurring opinion in Kappos v. Bilski and foster greater harmony between U.S. patent law and the patent law in Europe.

2. Enact a substitute, statutory eligibility standard that overrules the “implicit exception” and the two-part test used to implement it. The Court’s rationale for imposing a judicial exception fails to take full account of the collective effect of the set of statutory requirements that limit the availability of conceptual patents—the possibility that patents can either cover or preclude access to natural materials, laws, or phenomena. Maintaining a judicial exception is, therefore, unnecessary for any articulated constitutional or policy reason.

3. Exempt from patent infringement research uses of patented inventions where the exempted experimentation is limited to activities to better understand or improve the patented subject matter. Such an exemption should be limited and targeted in a manner that is consistent with the 2006 recommendation of the National Academies for doing so. This clarification that research performed on patented inventions is non-infringing would assure that no vestige remains of the Supreme Court’s justification for imposing a judicial eligibility exception.
The solution to this potential dilemma is by no means trivial. Each of these proposals was the product of a serious deliberative process that involved leading members of the IP community.

Anyone looking for a starting point for congressional intervention that would pick one proposal and disregard the others would immediately be confronted with the reality that the separate ABA IPL Section, IPO, and AIPLA § 101 initiatives each reflected truly prodigious, multi-year efforts within each of these organizations. The respective multi-year processes within each organization involved substantial task forces that were constituted with experienced patent practitioners, as well as academics. The task force work product in each case was ultimately adopted by the organization’s governing body, the council of the ABA IPL Section and boards of directors of the IPO and AIPLA—composed in each case of senior and respected members of the IP community.

A similar observation can be made with respect to the seriousness of the fourth effort. Following a two-day patent-experts conference held on November 19-20, 2016 at the Banbury Center Conference in Cold Spring Harbor, New York, a group of 18 conference participants from around the world issued a paper outlining a possible legislative approach for defining patent-eligible subject matter. In general, the Banbury patent experts—like the individuals involved from the ABA, IPO, and AIPLA—included notable proponents of strong and effective patent laws.

Finally, while the Banbury patent experts adopted an approach that differed significantly from the work of the other three organizations, the approach urged by the Banbury patent experts was mentioned approvingly by at least some participants in the USPTO Roundtable 2 on patent eligibility. In brief, no single approach at this juncture can be said to stand so much taller than the others that all but the one should recede from the policy debate.

Most importantly, however, serious and credible arguments have now been placed on the public record by these four entities, identifying various types of subject matter for which individuals and organizations noted for being serious and credible advocates for a strong patent system have urged should be excluded from patent protection. For any legislative effort that seeks a comprehensive codification superseding the “implicit exception” with explicit, statutory limitations on the reach of the U.S. patent system, the four extant proposals must be regarded as consensus limitations on what patents can legitimately protect—and, thus, must be aggregated into a synthetic whole for such a legislative effort to have any hope of being credible.

It appears to be inevitable, therefore, that any near-term legislative strategy for enticing action by Congress must give due regard to each of the four extant proposals and disregard none. If the necessary predicate to congressional action is for these four proposals to be melded together—to form the core of a unitary legislative effort to supersede the judicially imposed restrictions on the availability of enforceable patent rights through new statutory restrictions on

---

The Threshold Inquiry: The Choice of Mechanism for Limiting Patent Protection by Statute

Barring patent protection as proposed by the four entities could be accomplished through amendments to the patent statute that would take any one of several forms. While the Supreme Court has indicated that its “implicit exception” limiting patent protection is a patent eligibility-based constraint that represents an uncodified exception under § 101, there is no a priori requirement that a codification effort must operate to deny patent protection to certain types of subject matter on eligibility grounds—or specifically amend § 101 of the patent statute.

The same end could be accomplished, at least in part, through alternative means, such as amending 35 U.S.C. § 102 addressing the novelty requirement for patentability or 35 U.S.C. § 112(a) setting out the requirement for a sufficient disclosure in the patent specification. For example, the IPO’s “human activity” limitation on available protection could be cast as a § 102 patentability constraint. Notably, a claim directed to a natural product devoid of any human activity could be specifically barred from patenting under a § 102 amendment dealing with inherent anticipation—instead of being declared patent-ineligible subject matter under § 101. Similarly, the bar to a “preemptive” claim covering every means to achieving a useful end—as the ABA IPL Section has proposed to do—could be statutorily addressed under § 112(a) by declaring such claims to be non-enabled relative to the full scope of the protection being sought.

A third approach for denying patent protection through a statutory intervention could take the form of a claim construction limitation—rather than a patentability limitation—for doing so. Congress elected to use this type of limitation on patent protection in crafting the 1952 Patent Act. It enacted what is now 35 U.S.C. § 112(f) in order to respond to the Supreme Court’s Halliburton holding.

As noted above, 35 U.S.C. § 112(f) effectively superseded the Supreme Court’s invalidity holding in Halliburton by mooting the cited ground for invalidity through a claim construction limitation on so-called “means-plus-function” claims. Its statutory claim construction rule can apply to elements in a claim to a combination of elements that would otherwise be construed as limited only to a function without reciting the structure, material, or acts for performing the function.

Under § 112(f), the type of claim that Supreme Court found invalid in Halliburton (i.e., a claim to a combination of elements with an element of the claim expressed in this means-plus-function manner) can be construed in a sufficiently narrow manner that the Supreme Court’s holding of invalidity would be inapplicable. Specifically, under § 112(f), Walker’s otherwise invalid claim would have been limited to the corresponding means for performing the function set out in the Walker specification, as well as any equivalent means.

83 The various statutory changes proposed herein are appended to this paper.
The congressional approach in 1952 for redressing the Supreme Court’s jurisprudence in *Halliburton* has a clear applicability to recent Supreme Court decisions imposing the *Mayo/Alice* two-part test for defining the “implicit exception” to the subject matter that can be regarded as eligible for patenting under 35 U.S.C. § 101. The Supreme Court holdings establishing the “implicit exception” could be mooted—as well as the two-part test implementing them—were Congress to take the step of enacting a set of comprehensive § 112(f)-like limitations on claim construction, *i.e.*, so that the claim construction limitations on patent protection barred coverage for a law/product of nature, natural/physical phenomenon, or abstract idea or other such concept.

As will be detailed below, the ABA IPL Section, IPO, and AIPLA proposals are ideally suited to codification as claim construction limitations in preference to either subject matter eligibility or other patentability limitations. In contrast, the proposal of the Banbury patent experts is amenable to codification as an eligibility limitation on the subject matter that can be regarded as patentably useful, based on making a practical contribution to a field of technology.

**Codification of the IPO and AIPLA Proposals: New Claim Construction Limitations**

As noted above, the IPO proposed a pair of new statutory grounds on which subject matter could be denied patent protection, *i.e.*, the *human activity* and *human mind* limitations. Taking on the IPO’s proposed “human activity” limitation first, if claimed subject matter fails to reflect any human activity that has altered what otherwise would be a natural product or process, IPO urged that the claimed invention should be patent-ineligible.

This *human activity* limitation, although expressed by the IPO as a proposed § 101 eligibility bar to patenting duplicates—or at a minimum overlaps with—another long-recognized bar to patentability under current law. In *Peters v. Active Mfg. Co.*, the Supreme Court confirmed the existence of an inherent limitation on inventions that could be considered novel—which includes a natural law, product, or phenomena—under the doctrine of “inherent anticipation. The *Peters* doctrine provides: “‘That which infringes, if later, would anticipate, if earlier.’” For the purpose of applying this doctrine, it matters not whether the natural law/product/phenomena is newly discovered by the inventor or was long known to exist.

The potential overlap between the IPO proposal and existing § 102 novelty requirements suggests looking to a more workable alternative to what could prove to be an esoteric effort to amend § 102 to expressly bar patenting for subject matter that may already be inherently unpatentable under § 102. The *Halliburton* codification effort from 1952 may provide such a model. If Congress were willing to act to define by statute how an otherwise invalid claim could be salvaged as valid—as the Walker claim would have been under § 112(f)—the straightforward

---

85 The above rubric has been restated by the Federal Circuit as “[t]hat which would literally infringe if later in time anticipates if earlier than the date of [the patent filing].” *Levmar Marine, Inc. v. Barent, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987).
86 See *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1377 (Fed. Cir. 2003), “recognition by a person of ordinary skill in the art … is not required to show anticipation by inherency.”
route for doing so would be to limit the subject matter covered by an otherwise invalid claim to subject matter that might be valid under the patent statute.

The foregoing, therefore, suggests that the “human activity” limitation on patent protection that was proposed by IPO should be accomplished in a statutory codification that is not based upon subject matter eligibility or some other patentability limitation, but on a new limitation on claim construction. Under such an approach to codification, a properly construed claim would be limited such that it could not cover a law or product of nature or any natural or physical phenomenon. Inspired by § 112(f) under the 1952 Patent Act, and the text developed by the IPO in its proposal, such a new statutory claim construction limitation might read:

**Natural products and processes and other phenomena of nature.** — A claim that would otherwise cover subject matter that exists in nature independently of and prior to any human activity, irrespective of whether or not such subject matter was known to so exist prior to the effective filing date of the claimed invention, shall instead be construed to exclude coverage for all such naturally occurring subject matter.

A similar path exists for codification of IPO’s “human mind” limitation. Although it has been widely seen as a somewhat odd formulation for a statutory limit on patent eligibility, IPO has nonetheless squarely raised a very important issue relating to the availability of patent protection for subject matter that is, at its heart, *metaphysical* in character. While IPO’s proposal only addresses the more narrow issue of barring protection for entirely mental processes, it opens the door to discussing the broader question of the status that should be accorded to “mental steps” more generally in process claims. Among the questions that deserve a careful vetting and a clear answer: *To what extent should the content of human thought be a relevant element of proof to establish that a claim of a patent has been infringed? Should patent protection made available through process claims be confined to non-mental steps, thereby assuring that patent rights can never constrain the thought process of a human being?*

For a claimed invention that could be performed entirely in the human mind, it is at least arguable that a claim to such an invention would fail the § 112(a) disclosure test for patentability. *How can the words in a patent specification possibly both describe and enable every mental means, taking place solely in the human mind, for carrying out the entirely mental invention? Moreover, if an entirely mental process fails to pass muster under § 112(a), then a process containing one or more steps expressed in terms broadly enough to be carried out mentally would appear to have an identical § 112(a) defect—since sufficiency of disclosure is tested against the full scope of the protection being sought and applies step by step to a process.*

Any effort at codification based on the IPO proposal should first address the seminal question of whether patent protection should be unavailable if an individual step of a process claim has been drafted broadly enough to include performance of the step solely in the human mind, *e.g.*, based on non-enablement or other invalidity grounds. Thus far, as noted above, the Federal Circuit appears to regard claims with “mental steps” as simply patent eligible claims.
unless the claim as a whole is to an entirely mental process— with such claims not being subject to the limitations on claim construction under existing § 112(f). Again, as noted above, if the Federal Circuit’s view is correct, it could mean that a process that was patent-ineligible as an entirely mental process could be revived as patent-eligible by doing nothing more than adding some trivial and conventional step— such a conventional step of “announcing” or “recording” the result of the entirely mental process.

Depending of the answer to the above question, the soundest policy path forward for codification of the “human mind” proposal may be through a limitation on patenting of processes to those with non-mental, physical steps, thereby taking any machinations of the human mind entirely out of the calculus used to determine if a patent claim has been infringed. If so, claims drafted with steps that might be performed by doing nothing more than thinking could be confined— through new statutory provisions on claim construction— to the types of physical “acts” to which longstanding Supreme Court precedents suggest that a valid patent claim must be limited: “A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.”

By their nature, claim steps drafted in terms general enough to be capable of being performed by mere thinking might be regarded as sufficiently conceptual/functional in character that the claim may be invalid by analogy to (or simply extending or applying) Halliburton, absent the applicability of the limitation in existing § 112(f) to limit their construction to non-mental means (i.e., “acts”) for performing such a step. If so, Congress could be justified in specifically cabining the reach of mental steps in patent claims in a manner analogous to § 112(f)’s existing limitation for functional steps to “acts” given the absence of any viable precedents indicating that existing § 112(f) does so.

Finally, under existing § 112(f), multi-step process claims that set out a “step for” performing a particular function without also reciting the “acts” for carrying out the step are to be construed to cover only the “acts” set out in the patent specification for performing the steps of the claim. While § 112(f) covers only multi-step process claims, i.e., combination claims, there is no conceivable policy reason to limit the existing § 112(f) cabining of process claims with steps stated in such functional terms solely to multi-step processes.

This suggests that any addition to using a § 112(f) approach to address the issue of mental processes, a new § 112(f)-like provision should more generally address all process claims limited only by functionally expressed steps, irrespective of whether or not the process claims are of a “combination” (i.e., multi-step) character. To this end, the following statutory provision on

87 See CyberSource Corp. v. Retail Decisions, Inc., supra, at 654 F. 3d 1373.
88 Cochrane v. Deener, 94 U.S. at 788.
89 “The process requires that certain things should be done with certain substances, and in a certain order …” Cochrane v. Deener, 94 U.S. at 788. See also Tilghman v. Proctor, 102 U.S. 707, 728 (1881), “A machine is a thing. A process is an act, or a mode of acting. The one is visible to the eye,— an object of perpetual observation. The other is a conception of the mind, seen only by its effects when being executed or performed.” [Emphasis added.]
claim construction would assure that the “mental” subject matter IPO would bar from patenting on eligibility grounds would be removed from the scope of protection under a process patent on claim construction grounds—as well as maintain and further amplify the existing provision of § 112(f) addressing functionally defined process steps:

MENTAL OR FUNCTIONAL STEPS.—A step in a claim to a process, which step could be construed to cover the performance of the step solely in the human mind, or recites a function without also reciting acts for carrying out the function and would otherwise cover every means for achieving the function, shall instead be construed to exclude coverage for performing the step mentally and to be limited to the corresponding acts described in the specification for carrying out the step and equivalents thereof.

If the issue of functionally defined process steps were to be addressed in a separate paragraph of § 112(f), as above, that did not deal with machines, manufactures, and compositions of matter claimed with functionally defined elements, then existing § 112(f) would need to be redrafted to set out the claim construction limitations for non-process claims. Redrafting existing § 112(f) for such product claims would then afford Congress the opportunity to address problematic aspects of the current jurisprudence implementing § 112(f) that imposes unneeded presumptions as to the applicability of existing § 112(f) to a particular claim.

A claim element under current § 112(f) is presumed to be subject to § 112(f)’s claim construction limitation if the claim element recites the word “means” together with functional language. However, this presumption can be overcome if the claim element then recites further structure necessary to perform the stated function.90 On the other hand, absent literally reciting the word “means” in the claim element, a rebuttable presumption is created that § 112(f) is inapplicable. However, this rebuttable presumption too can then be overcome whenever “the claim term fails to ‘recite sufficiently definite structure’ or else recites ‘function without reciting sufficient structure for performing that function.’”91

Given that the justification for the presumption lies judicial holdings that the word “means” as used in current § 112(f) was intended by Congress to have a presumptive significance if repeated—or not—verbatim in a claim, a redrafted § 112(f) could streamline the current, presumption-laden § 112(f) analysis of a claim element by simply forcing that the claim be construed in a presumption-free manner and letting the resulting claim construction determine whether the claim must be construed in the § 112-limited manner based on its functional character. New § 112(f) language to accomplish this end could take the following form:

FUNCTIONAL ELEMENTS IN COMBINATION CLAIMS.—An element in a claim to a combination of elements, other than a claim

90 See TriMed, Inc. v. Stryker Corp., 514 F.3d 1256, 1259-60 (Fed. Cir. 2008), “Sufficient structure exists when the claim language specifies the exact structure that performs the function in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure.”

to a process, which element recites a function without reciting the structures or materials for achieving the function and would otherwise cover every means for achieving the function, shall instead be construed to cover only the corresponding structures or materials described in the specification and equivalents thereof.

**Codification of the ABA IPL Section Proposal: A New Claim Construction Limitation**

As noted above, the ABA IPL Section resolution addresses the issue of patent ineligibility when the claim as a whole is preemptive of a concept, i.e., a natural law or phenomenon or abstract idea or concept otherwise. The ABA IPL Section resolution can be thought of as applying the invalidity ground in *Halliburton* relating to overly broad functional elements in combination claims to any preemptively broad claim, when considered as a whole. The parallels between functional and preemptive claiming suggest a potential ease in crafting a § 112(f)-type preemption limitation using existing § 112(f) as its drafting model.

In particular, given the other claim construction limitations set out above, a new ABA IPL Section-inspired § 112(f) “preemption” limitation could apply in situations where the other new § 112(f) claim construction limitations above failed to eliminate the possibility for preemption. Such a situation might arise for any claim construed as a “single means” claim.92

To this end, 35 U.S.C. § 112(f) could be amended to additionally include the following paragraph:

**PREEMPTIVE CLAIMS.**—A claim that, notwithstanding the limitations under the above paragraphs, would nonetheless be construed to cover every useful application of a natural law or phenomenon or other abstract idea or concept shall instead be construed to cover only the specific means for implementing the idea or concept that are described in the specification and that otherwise meet each of the limitations in the claim.

This alternative to the ABA IPL Section § 101 eligibility resolution—as is the case with existing provision in § 112(f)—would have the advantage of preserving the validity of a claim that otherwise would have extended protection so expansively as to run afoul of longstanding “insufficiency of disclosure” principles, e.g., as is the case with the § 112(a) invalidity of

---

92 The Massachusetts District Court in *Amgen v. Chugai*, 13 USPQ2d 1737, 1774 (DC Mass. 1989) offered a definition of a “single means” claim:

“single-means” claims.\textsuperscript{93} Specifically, claims of this type that would otherwise impermissibly extend to all useful (\textit{i.e.}, practical) applications of a concept are in effect cut down to a “valid” size—just as existing § 112(f) does for combination claim elements defined functionally.

\textbf{A New 35 U.S.C. § 112(f) Addressing the “Implicit Exception” Through Claim Construction}

With new claim construction language used to statutorily address the human mind/human activity limitations, as well as preemptive claims, the existing text of 35 U.S.C. § 112(f)\textsuperscript{94} could be expanded by combining the four separate paragraphs detailed above into a comprehensive statutory provision on claim construction that addresses each of the new statutory limits on patenting proposed by the ABA IPL Section, IPO, and AIPLA. In its complete form, such a new § 112(f) would read:

\begin{quote}
(f) \textbf{CLAIM CONSTRUCTION},—
\begin{enumerate}
\item \textbf{NATURAL PRODUCTS AND PROCESSES AND OTHER PHENOMENA OF NATURE}.—A claim that would otherwise cover subject matter that exists in nature independently of and prior to any human activity, irrespective of whether or not such subject matter was known to so exist prior to the effective filing date of the claimed invention, shall instead be construed to exclude coverage for all such naturally occurring subject matter.
\item \textbf{MENTAL OR FUNCTIONAL STEPS}.—A step in a claim to a process, which step could be construed to cover the performance of the step solely in the human mind, or recites a function without also reciting acts for carrying out the function and would otherwise cover every means for achieving the function, shall instead be construed to exclude coverage for performing the step mentally and to be limited to the corresponding acts described in the specification for carrying out the step and equivalents thereof.
\item \textbf{FUNCTIONAL ELEMENTS IN COMBINATION CLAIMS}.—An element in a claim to a combination of elements, other than in a claim to a process, which element recites a function without reciting the structures or materials for achieving the function and would otherwise cover every means for achieving the function, shall instead be construed to cover only the corresponding structures or materials described in the specification and equivalents thereof.
\end{enumerate}
\end{quote}

\textsuperscript{93} See \textit{In re Hyatt}, 708 F. 2d 712, 714 (Fed. Cir. 1983), “The long-recognized problem with a single means claim is that it covers every conceivable means for achieving the stated result, while the specification discloses at most only those means known to the inventor. \textit{See O’Reilly v. Morse}, 56 U.S. 62, 112, (1853). Thus, the claim is properly rejected for what used to be known as ‘undue breadth,’ but has since been appreciated as being, more accurately, based on the first paragraph of § 112.”

\textsuperscript{94} The existing statutory text reads:

\begin{quote}
(f) \textbf{ELEMENT IN CLAIM FOR A COMBINATION}.—An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.
\end{quote}
(4) **PREEMPTIVE CLAIMS.**—A claim that, notwithstanding the limitations under paragraphs (1) through (3), would nonetheless be construed cover every useful application of a natural law or phenomenon or other abstract idea or concept shall instead be construed to cover only the specific means for implementing the idea or concept that are described in the specification and that otherwise meet each of the limitations in the claim.

The upshot of the foregoing set of claim construction provisions is two-fold. First, it fully addresses all the issues of patent protection that the ABA IPL Section, IPO, and AIPLA collectively proposed be addressed as patent eligibility bars. The subject matter that these organizations would bar from patenting on eligibility grounds would be efficiently excluded from patent protection as a matter of claim construction, thereby potentially preserving the patentability of the claims so construed.

Second, and most importantly, any possible justification for the Supreme Court’s “implicit exception” to eligibility for patenting under 35 U.S.C. § 101 would be obviated under these new statutory limitations on claim construction. Natural products, processes, laws, and phenomena would be excluded from the scope of patent protection by explicit statutory limitations on what a patent claim might be construed to cover. Similarly, patents could not extend to protect any abstract idea or other concept. The final limitation on presumptive claims would assure claims that might otherwise preempt all practical applications of a concept would be strictly limited to the means described in the patent for implementing the concept. There would remain no possibility that a patent’s protection would extend to cover—or otherwise preclude access to—the basic tools of science and technology.95


To further cement this statutory codification and most assuredly moot the judicially imposed “implicit exception” to patent eligibility, existing § 101 could be amended to reflect that patentability is now exclusively defined through statutorily explicit requirements for patentability. Instead of providing that a patent **may be obtained** subject to the statutory

---

95 As proposed in the Banbury Center Conference statement discussed below, Congress should enact a “research use” exemption to infringement as a further means to this end. The proposed statutory provision for doing so follows (almost verbatim) the National Academies’ recommendation in this respect (see *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health*, [http://www.nap.edu/catalog/11487.html](http://www.nap.edu/catalog/11487.html)). It would add a new subsection (j) to 35 U.S.C. § 271:

(j) EXPERIMENTAL USES OF CLAIMED INVENTIONS.—Notwithstanding subsections (a) and (g), it shall not be an act of infringement to make or use a claimed invention for experimental purposes to discern or discover

(1) the validity or scope of protection of a patent for the claimed invention;
(2) any feature, property, characteristic, advantage, or disadvantage of the claimed invention;
(3) any method of making or using the claimed invention;
(4) any alternative to, improvement to, or substitute for the claimed invention.
conditions and requirements, an amended § 101 can—and should reflect—the inventor’s right to a patent if such conditions have been met:

> Whoever invents a useful process, machine, manufacture, or composition of matter, or a useful improvement thereto, shall be entitled to a patent on such invention absent a finding that one or more conditions or requirements under this title have not been met.

The above text would incorporate into § 101 the same statutory “right to patent” principle that was originally present in § 102’s preamble, as enacted under the 1952 Patent Act. Under the 1952 Patent Act, § 102 provided that an inventor has a right to a patent absent some finding that one or more of the conditions and requirements for patentability has not been met. This is best illustrated in the text of now-repealed § 102(f) of the 1952 Patent Act that obligated the United States Patent and Trademark Office to allow a patent to be granted to an inventor on an inventor’s claimed invention. Since the enactment of the Leahy-Smith America Invents Act in 2011, there has been no cogent provision in the patent statute providing the inventor the same categorical right to patent formerly appearing in the pre-AIA § 102(f). The above text of § 101 would remedy this drafting deficiency in the AIA.

**Codification in 35 U.S.C. § 101 of the Banbury “Contribution to a Field of Technology” Test**

To implement the recommendations in the statement of the Banbury Center Conference patent experts in a manner to provide the utmost in clarity for any new statutory framework under amended § 101, it would be optimal if any new statutory language were to clarify that the patent laws are limited to protecting inventions with the appropriate quantum of usefulness. In this regard, as discussed above, Supreme Court and Federal Circuit precedents have limited patentable inventions to those evidencing a practical use.

Marrying these utility-related legal precedents with the Banbury Center Conference’s proposal, a full codification of the “usefulness” requirement for patentability should provide that a claimed invention can be regarded as being useful under the patent statute only if it makes a practical contribution to a field of technology. Incorporating into § 101 of the reference in the

---

96 Under § 102(f) enacted under the 1952 Patent Act, “A person shall be entitled to a patent unless … he did not himself invent the subject matter sought to be patented”

97 In re Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984) and In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992), “If examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent.”

98 Specifically, in rewriting § 102 as an entirely new provision of title 35, the AIA left the opening clause of subsection (a) of this section unchanged from the text of § 102 as enacted under the 1952 Patent Act. However, under the AIA, each of the loss of right to patent provisions were removed from § 102, including § 102(f). As a result, the current opening clause of § 102(a) has no readily apparent purpose and affords no predicate—including appropriate antecedents—for the substantive text that follows.

99 The amended § 101 set out above allows a conforming and correcting amendment to be made to § 102(a) that aligns its preamble with that of § 103, namely “A patent for a claimed invention may not be obtained if”—for the term “claimed invention.”

100 As noted above, the requirement for a practical use has been extensively developed by the Federal Circuit. See In re Fisher, supra, which followed the Supreme Court precedent in Brenner v. Manson, supra.
recommendations of the Banbury Center Conference patent experts to a field of technology is appropriate both for consonance with international treaty obligations of the United States and for constitutional reasons.

Any restrictions on patenting in the United States—whether limitations on subject matter eligibility, patentability otherwise, or claim construction—should be consistent with the “patent availability” criteria under the TRIPS agreement. TRIPS requires availability of patents in all fields of technology, without limitation or restriction. Placing a reference in § 101 to practical contributions to a field of technology should provide additional assurance that the scope of the U.S. patent system is coextensive with the U.S. treaty obligations under TRIPS.

The reference to field of technology should also assure constitutionality—given that Congress has the power under the U.S. Constitution to secure protection for inventors under Article I, Section 8, Clause 8 only for the purpose of promoting progress in the useful arts. In this regard, “[n]umerous scholars have suggested that the term ‘useful arts’ was widely understood to encompass the fields that we would now describe as relating to technology or ‘technological arts.” In addition, the text of various Federal Circuit opinions have suggested that patent-eligible inventions must have a technological character. This additional statutory specificity could best take the form of a second sentence (italicized below) added to the text for § 101 proposed above:

§ 101. Right to patent eligible inventions.

Whoever invents a useful process, machine, manufacture, or composition of matter, or a useful improvement thereto, shall be entitled to a patent on such invention absent a finding that one or more conditions or requirements under this title have not been met. A claimed invention shall be regarded as being useful under this title only if it makes a practical contribution to a field of technology.

---


102 Article I, Section 8, Clause 8, of the U.S. Constitution, Congress is permitted to act “To promote the Progress of … useful Arts, by securing for limited Times to … Inventors the exclusive Right to their respective … Discoveries….”


104 “Alice Corporation v. CLS Bank International, 134 S.Ct. 2347, 2356-59 (2014), for all intents and purposes, set out a technological arts test for patent eligibility. Because the purported inventive concept in [the adjudicated] asserted claims is an entrepreneurial rather than a technological one, they fall outside section 101.” Judge Mayer, concurring, Ultramercial, Inc. v. HULU, LLC, 772 F. 3d 709, 717 (Fed. Cir. 2014). “Alice articulated a technological arts test for patent eligibility. 134 S.Ct. at 2359 (explaining that the claimed method fell outside section 101 because it did not ‘improve the functioning of the computer itself’ or ‘effect an improvement in any other technology or technical field’).” Judge Mayer, dissenting, DdR Holdings, LLC v. Hotels. Com, LP, supra, at 773 F. 3d 1265.
The inclusion of such a field of technology limitation in § 101 should further contribute to reaching the political consensus needed for any successful legislative effort to supersede Supreme Court precedent with a new statutory provision. As noted above, the final report of the United States Patent and Trademark Office following its Roundtable 2 on Patent Eligibility indicates at least some support for such a codification.

Conclusions

The efforts of the ABA IPL Section, IPO, and AIPLA on patent eligibility have provided the opportunity for a constructive dialogue on how best to amend the patent statute to address recent Supreme Court decisions on patent eligibility. While efforts thus far have been focused on amending § 101 of the patent statute, new § 101 eligibility limitations are neither the sole—nor necessarily the preferred—mechanism for codification of such patent-limiting principles. The response by Congress to the 1946 Halliburton decision—in enacting what is now § 112(f) of the patent statute—offers a potentially superior approach to codification. Just as § 112(f) was designed to moot the Supreme Court’s Halliburton decision as a ground for invalidating patents, an expanded § 112(f) could moot the Supreme Court’s “implicit exception” jurisprudence.

Through concise statutory language using existing § 112(f) as a model, a new claim construction provision could categorically bar patent protection for any law/product of nature, natural/physical phenomenon, or abstract idea or other concept—leaving no remaining rationale for a judicially imposed “implicit exception” that would render subject matter of this ilk patent ineligible. Contemporaneously with the enactment of such a § 112(f)-like remediation, Congress has the opportunity to more fully embed the constitutional foundation of the patent system into the Patent Act.

It could do so by adding to § 101 a provision explaining the nature of inventions that can promote progress in the useful arts based on their practical usefulness. Self-evidently, promoting progress in the useful arts exists whenever a claimed invention makes a practical contribution to a field of technology. For the above synthesis of competing proposals to become law, it must survive intense vetting. Any action to amend a statute is fraught with the potential for producing unintended consequences and for failing to achieve its intended ones. The above proposal, however, was designed in a manner to eliminate any realistic possibility for the latter and minimize the likelihood of the former.

Also, any change to U.S. patent laws has the potential to move the U.S. patent system away from international norms, making it more difficult for inventors to have common, predictable and effective strategies for securing global patent protection. The above proposal was designed with features that recognize, rather than refute, international norms for patenting, albeit in the context of the constitutionally limited authorization given to Congress to write the domestic patent laws.

Lastly, any action by Congress addressing an area of great controversy must be done mindful of the need for it to be recognized and accepted as both principled and palatable to a wide spectrum of diverse interests. The present proposal was conceived with the ambitious purpose that it might be acceptable to all and disdained by none.
APPENDIX: SUPERSETING THE “IMPLICIT EXCEPTION” TO PATENT ELIGIBILITY
HARMONIZING THE ABA, IPO, AIPLA, AND BANBURY CONFERENCE INITIATIVES ON § 101 REFORM

The ABA IPL Section, IPO, AIPLA, and a group of patent experts at a recent Banbury Center Conference have tabled four different concepts for addressing the Supreme Court’s jurisprudence that imposes an “implicit exception” on subject matter eligible for patenting under 35 U.S.C. § 101. While the four approaches differ in various respects, each shares a common vision. Each would supersede the judicially imposed limitations on subject matter eligibility through new statutory provisions. The ABA IPL Section seeks to render claims patent ineligible that preempt every practical application of a natural/physical phenomenon or abstract idea. The IPO and AIPLA insist that ineligibility should instead be confined to inventions evidencing no human activity or inventions carried out entirely though human thought. The Banbury patent experts urge that patenting be limited to inventions contributing to a field of technology. The statutory text below is an effort to harmonize these four approaches into a unitary statutory framework, with the aim of seeking a broad consensus on a single legislative path forward:

(a) LIMITATIONS ON CLAIM CONSTRUCTION.—Strike section 112(f) and insert:
“(f) CLAIM CONSTRUCTION.—
“(1) NATURAL PRODUCTS AND PROCESSES AND OTHER PHENOMENA OF NATURE.—A claim that would otherwise cover subject matter that exists in nature independently of and prior to any human activity, irrespective of whether or not such subject matter was known to so exist prior to the effective filing date of the claimed invention, shall instead be construed to exclude coverage for all such naturally occurring subject matter.
“(2) MENTAL OR FUNCTIONAL STEPS.—A step in a claim to a process, which step could be construed to cover the performance of the step solely in the human mind, or recites a function without also reciting acts for carrying out the function and would otherwise cover every means for achieving the function, shall instead be construed to exclude coverage for performing the step mentally and to be limited to the corresponding acts described in the specification for carrying out the step and equivalents thereof.
“(3) FUNCTIONAL ELEMENTS IN COMBINATION CLAIMS.—An element in a claim to a combination of elements, other than in a claim to a process, which element recites a function without reciting the structures or materials for achieving the function and would otherwise cover every means for achieving the function, shall instead be construed to cover only the corresponding structures or materials described in the specification and equivalents thereof.
“(4) PREEMPTIVE CLAIMS.—A claim that, notwithstanding the limitations under paragraphs (1) through (3), would nonetheless be construed cover every useful application of a natural law or phenomenon or other abstract idea or concept shall instead be construed to cover only the specific means for implementing the idea or concept that are described in the specification and that otherwise meet each of the limitations in the claim.”

(b) RIGHT TO PATENT ELIGIBLE INVENTIONS.—Strike section 101 and insert:
“§ 101. Right to patent eligible inventions.
“Whoever invents a useful process, machine, manufacture, or composition of matter, or a useful improvement thereto, shall be entitled to a patent on such invention absent a finding that one or more conditions or requirements under this title have not been met. A claimed invention shall be regarded as being useful under this section only if the claimed invention makes a practical contribution to a field of technology.”