May 14, 2012

Prometheus' Revenge: Process Patent Ambiguity

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Abstract

In Mayo Collaborative Services v. Prometheus Laboratories, Inc., the Supreme Court returned to historical roots to determine whether a process met the subject matter criteria requirement for patents. The decision to return to historical precedent demonstrates two things: 1) the Court is hesitant to adopt black letter tests for determining patent eligibility and 2) the Court doubts the future applicability of the transformation component of the machine-or-transformation test as technology progresses. Because the decision did not provide any true guidance or light as to how a process claim should be analyzed for subject matter eligibility, the eligibility of such patents remains in the dark. As binding authority, this decision will shape and alter how patents are scrutinized and how companies will conduct their research and business strategies in the future.

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Introduction

The legend of the Greek Titan, Prometheus, claims that an enraged Zeus took fire away from mortals in retribution for faulty sacrifice. Prometheus, a champion of man, stole fire from Zeus and reinvested man with this gift and the power to use it. Prometheus was eternally and brutally punished for these actions.\(^1\) Man, on the other hand, was forever empowered. The power of fire granted man the ability to warm himself, to cook his food, and to build civilizations. Most importantly, Prometheus’ gift gave man the ability to light his way, to see clarity where he once was surrounded by dark.

Leaping thousands of years later to present day, the patent world finds itself in a dim place without a flame to light its path. On June 28, 2010, the Supreme Court of the United States, the “Titans” of the American legal system, handed down its decision of *Bilski v. Kappos.*\(^2\) This decision blunted a useful tool for determining patent eligibility of process patents, the machine-or-transformation test. Prior to this ruling, a method or process was patentable subject matter if it satisfied one of the two prongs of this test: 1) the method or process is attached to a machine or apparatus, or 2) it transforms a particular article into a different state or thing.\(^3\) This stood for a long time as a clear test that allowed inventors, patent attorneys, and potential infringers to gauge if a process or method would be eligible for patent protection prior to infringement or litigation. Despite the obvious clarity provided by the test, the Court ruled that the machine-or-transformation test is but a useful clue, not the *sole* indicator for a process to be patent-eligible subject matter.\(^4\) This decision created a void in the area of patent eligibility because it did not supply the legal field with further factors or other clear-cut tests to use. Thus,

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\(^1\) *The Theogony of Hesiod* 507-43 (Hugh G. Evelyn-White trans., 1914). The legend of Prometheus indicates that as punishment for Prometheus’ theft of fire to gift it to man, Zeus chained him to a rock to have a great eagle peck out his liver every day only to have it grow back and be eaten again the next day.


\(^3\) *Id.* at 3225.

\(^4\) *Id.* at 3226.
this hasty decision by our Legal Titans mirrored that of Zeus, taking fire away from the mortals, and leaving us in the dark about the eligibility of process patents.

Just one year after Bilski was decided, another process patent case, Mayo Collaborative Services v. Prometheus Laboratories, Inc. (“Prometheus”), made its way to the Supreme Court for these Titans to cast judgment.\(^5\) It was believed that hope existed for the mortals of the patent world. After all, a case with the very same namesake of Prometheus, the giver of fire, arose with the ability to grant the needed clarity where darkness lies: the ability to determine—or at least make an educated guess—if a claimed process meets the criteria to be patent eligible subject matter. The patent at the heart of Prometheus claimed a process or method of correlating blood tests to patient health.\(^6\) Originally, Mayo Collaborative Services (Mayo) licensed the process from Prometheus Laboratories, Inc., (Prometheus) and used the process to diagnose its patients by measuring their levels of thioguanine metabolites.\(^7\) After several years of licensing, Mayo ceased the licensing agreement with Prometheus and began offering similar services under its own devised method, leading to this infringement suit.\(^8\) The Federal Circuit overturned the district court, finding patent eligibility through the machine-or-transformation test.\(^9\) Mayo appealed the decision to the Supreme Court and a slew of *amici* joined in support of and opposition to the patent’s validity.

The recent arguments in the Supreme Court actually marked the second time that Prometheus cast its eyes on the Court. Prometheus I, which was pending on *writ* while the Court decided Bilski, was remanded back to the Federal Circuit to be decided in light of that decision.\(^10\) The Federal Circuit reaffirmed its stance in Prometheus II, and that decision was like-wise

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\(^{6}\) *Id.* at 1290.

\(^{7}\) *Id.* at 1290—91.

\(^{8}\) *Id.* at 1291.

\(^{9}\) *Id.*

followed by appeal and writ to the Supreme Court.\textsuperscript{11} The Court granted the petition for certiorari, and the case was argued on December 7, 2012.\textsuperscript{12}

On March 20, 2012, the Supreme Court handed down its unanimous decision penned by Justice Breyer. The Court ruled the patent an invalid attempt to patent a process that claimed little more than a realization of a law of nature.\textsuperscript{13} The Court refused to elaborate on its view of the machine-or-transformation test after its \textit{Bilski} decision. Instead the Court used a law of nature analysis so that it could ignore the questions about of the machine-or-transformation test that had arisen from its decision in \textit{Bilski} and were discussed by the lower courts in \textit{Prometheus}. Ultimately, a lesson was learned from the Prometheus legend: \textit{no good deed goes unpunished}. Fearing that any elaboration could be mistakenly interpreted as a new categorical test, the Court erred on the side of caution. No new “fire” was to come from this decision that might bring clarity to process patent eligibility.

This Note aims to illustrate the current state of process patent ambiguity caused by vaguely written laws and conflicting jurisprudence. To this end, Part I will discuss the patent-eligible subject matter of Section 101 and provide a cursory analysis of the history and jurisprudence governing process patents. Part II will focus on the machine-or-transformation test from its inception through its ultimate downfall in \textit{Bilski}. Part III will track and examine the applicable laws and arguments in \textit{Prometheus} from the district court up through its final arguments in front of the Supreme Court. This section will ultimately conclude on the Court’s decision to invalidate the patent and its refusal to address the current role or applicability of the machine-or-transformation test. Part IV will analyze and tie together the previous sections in

\begin{footnotesize}
\textsuperscript{11} Mayo Collaborative Services v. Prometheus Laboratories, Inc., 628 F. 3d. 1347 (Fed. Cir. 2010), reversed by, 132 S. Ct. 1289 (2012).
\textsuperscript{12} Mayo Collaborative Services v. Prometheus Labs., Inc., 131 S. Ct. 3027 (2011).
\textsuperscript{13} \textit{Prometheus}, 132 S. Ct. 1289 (2012).
\end{footnotesize}
order to determine the current state of affairs for process patents. This section will illustrate the need for the Supreme Court to provide guidelines on process patents so that lower courts and the rest of the patent world will have the tools needed to adequately scrutinize these patents. The analysis will primarily focus on the case’s influence on patent law; however, it will also attempt to explore some of the ways that this decision will impact the United States at large and will pay additional consideration to its effects on medical treatment programs and their patients.

**PART I. SECTION 101: PATENTABLE SUBJECT MATTER**

A. HISTORY OF SECTION 101.

The dissemination of ideas, technology, and invention for the public good is the single most important reason—the “why”—for all of the laws covering patents and copyrights. Realizing this principle, the founding fathers saw the need to incentivize invention and creativity in order to ensure that the information would eventually be distributed to the public for its own use.\(^{14}\) Accordingly, the framers of the constitution constructed Art. 1, § 8, cl. 8 to grant Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”\(^{15}\) The powers delineated in this clause have given rise to modern copyright and patent laws by allowing Congress to vest inventors and creators with a limited exclusive right, or monopoly, of their work in exchange for the public dissemination of their ideas. This dissemination is best ensured by the modern patent act whereby an inventor fully discloses his invention and the means of using it to the United States Patent and Trademark Office (USPTO), and thus to the public, in order to secure a monopoly-by-law\(^{16}\) on his creation for a period of twenty years. The

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\(^{14}\) 5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871).  
\(^{15}\) U.S. Const. art. 1, § 8, cl. 8  
\(^{16}\) Monopoly-by-law is a reference to the twenty-year monopoly granted to the patent holder in exchange for the dissemination of his idea to the public. This monopoly is granted by the Patent Act and carries with it the force of
public must understand that an inventor cannot be required by law to disclose his invention unless he seeks a patent. Therefore, without this monopolistic incentive granted to patents by the Federal Government, companies and inventors would be all the more likely to keep the invention as a trade secret, allowing them the sole beneficiaries of that invention as long as the information does not become known to the public.

While innovation and the dissemination of those ideas into the public domain remain the two fundamental driving forces behind patents, Congress and the courts realized that certain limitations must be placed on patents in order to ensure that the monopoly carried by the patent does not unreasonably foreclose on too broad of a principle. In an attempt to limit protection to the “Sciences and Useful Arts,” Congress has mandated that an invention must pass several criteria to be deemed worthy of patent protection. As the number of patents has increased through the years, the number of requirements has also expanded, now entailing that the patent convey novelty, utility, and specificity of claims; however, one constant is that patent protection has always been limited to certain types of subject matter. The original Patent Act of 1790 limited its protection to inventors that “have invented or discovered any useful art, manufacture, engine, machine, or device, or any improvement therein.” Just three years later, Thomas Jefferson, a founding father and future president, authored the amended Patent Act of 1793 with the philosophy that “ingenuity should receive a liberal encouragement.” Jefferson’s Act authorized patent protection to “any new and useful art, machine, manufacture or

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21 5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871).
composition of matter, or any new or useful improvement therein.” This amendment clarified a further requirement that the proposed invention be both new and useful, setting the stage for the novelty and utility requirements we have today.

Jefferson’s mark on patent eligible subject matter remained unchanged for over one hundred and fifty years until Congress passed the Patent Act of 1952. For the purposes of this paper, the most pertinent change in the Patent Act was the decision to replace the term “art” with “process” in 35 U.S.C.S. § 101 Patentable Subject Matter. This section, which has not been further amended since 1952, currently reads: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

The amendment of “art” to “process” by the 1952 Act did not change the substance of the law, but rather acted to clarify those inventions that are eligible subject matter. 35 U.S.C.S. § 100(b) defines the inserted term "process" as “process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.” By adding this circular definition, Congress effectively did not invalidate former “useful art” patents; rather, it used the term “process” to include those previous “art” patents while clarifying that the original term was designed to encompass process or method patents as well.

The “conditions and requirements of this title” discussed in section 101 refer to the section 102 non-obvious and section 103 novelty requirements also implemented by the 1952 Act. One may easily confuse these requirements as being redundant by noting that section 101 itself only grants eligibility to subject matter that is “new and useful.” However, each of these three provisions is a distinct and explicit requisite to patentability. As indicated by the legislative
history of section 101, Congress did not intend the "new and useful" language of section 101 to constitute an independent requirement of novelty or non-obviousness distinct from the more specific and detailed requirements of 35 U.S.C.S. §§ 102 and 103, respectively.\textsuperscript{25} Moreover, this matter was specifically discussed by the Supreme Court in \textit{Diamond v. Diehr}, which noted that although section 101 refers to “new and useful” processes, it is “overall a general statement of the type of subject matter that is eligible for patent protection subject to the conditions and requirements of this title.”\textsuperscript{26} The Court elaborated that in determining the eligibility of a claimed process for patent protection under section 101, claims must be considered as a whole, particularly in a process claim because a new combination of steps in the process may be patentable even though all the constituents of the combinations were well known.\textsuperscript{27} Under this reasoning, the “‘novelty’ of any element or steps in the process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the categories of possibly patentable subject matter under [section] 101.”\textsuperscript{28}

Clearly, Congress has delineated that only certain types of subject matter or types of inventions deserve the monopoly granted to patents. Section 101 is in place to illustrate these types of subject matter that can be eligible for patent protection if it is found that the invention as a whole meets all the other requirements imposed by the Act. However, that is not to underscore the importance of section 101 as a gatekeeper to patent eligibility—after all, “whether a claim is drawn to patent-eligible subject matter under 35 U.S.C.S. § 101 is a threshold inquiry, and any claim of an application failing the requirements of 35 U.S.C.S. § 101 must be rejected even if it

\textsuperscript{25} Id.
\textsuperscript{26} Diamond v. Diehr, 450 U.S. 175, 189 (1981).
\textsuperscript{27} Id. at 188.
\textsuperscript{28} Id. at 187—88.
meets all of the other legal requirements of patentability."  

B. SCOPE OF 35 U.S.C.S. 101

The issue of patent eligible subject matter remains the first “threshold” step a court should apply in the examination of a patent. It is clear by the repetitive inclusion of the word “any” in section 101 that Congress constructed the provision to be liberally construed. Indeed, the Supreme Court has followed this principle and has “consistently construed §101 broadly.” The Supreme Court has stated that “by choosing expansive terms to specify four independent patent-eligible categories of inventions of discoveries—processes, machines, manufactures, and compositions of matters—and by modifying those terms with the comprehensive ‘any,’ Congress plainly contemplated that §101 would be given wide scope.” Furthermore, in Diamond v. Chakrabarty, the Supreme Court noted that the Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man." However, the Court went on to delineate that limits to patentable subject matter do exist under section 101 so that it is not construed to embrace every discovery. For ease of reference, the interests of this paper would be better served by explaining what does not qualify as patentable subject matter prior to illustrating what has been deemed to qualify by the courts.

1. WHAT LIES OUTSIDE THE SCOPE OF PATENTABLE SUBJECT MATTER

In order to understand what is patentable subject matter, one must have a grasp on what

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29 In re Bilski, 545 F. 3d at 950.
30 See 35 U.S.C.S. 101 (1952). "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." (emphasis added).
31 Prometheus, 628 F. 3d 1347, __ (Fed. Cir. 2010), reversed by, 132 S. Ct. 1289 (2012).
32 Id.
34 Id.
has been identified or deemed to remain outside the scope of section 101. According to committee reports, Congress intended for section 101 to encompass everything under the sun made by man.\textsuperscript{35} While this statement might seem all-inclusive, it actually poses a large limitation on patent eligible subject matter—made by man—that has been the crux of numerous cases. The very same Court that noted Congress’ intent to broadly interpret the scope of § 101 in \textit{Chakrabarty} also coined the trilogy of categorical exclusions: laws of nature, physical phenomena, and abstract ideas.

Since this decision, the Supreme Court has clearly and consistently held that "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."	extsuperscript{36} Such fundamental principles as the laws of nature, natural phenomena, and abstract ideas are considered “part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.”\textsuperscript{37} While laws of nature and abstract ideas might lie outside of the realm of patent eligible subject matter, new and useful applications of these fundamental principles can be eligible for patent protection. Stated more eloquently, “He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.”\textsuperscript{38} Surely, if one were to discover a new species of plant or bacterium, a new element, or scientific law, the discovery has the potential to influence all of mankind and technology. However, the discovery would not suffice as an invention by man, but an invention by nature, and would thus not be eligible for patent protection.

\textsuperscript{36} \textit{Gottschalk} v. \textit{Benson}, 409 U.S. 63, 67 (1972).
\textsuperscript{38} \textit{Id.} (emphasis added).
Funk Brothers Seed Co. v. Kalo Inoculant Co. stands as one of the best and oldest examples of the Supreme Court invalidating a patent because its subject matter constituted a trivial implementation of a phenomenon of nature. The requisite facts to understand this case include the notion that leguminous plants, such as beans and peas, require some form of bacterium from the genus *Rhizobium* in order to effectuate certain chemical reactions necessary for its viability. Furthermore, different leguminous plants require different types of the bacterium. The patentee in this case discovered that six forms of *Rhizobium* could be bundled together into one product that would cover the spectrum of needs by the different types of legumes. Even though the idea proved effective, the Court ruled the product patent invalid, stating:

> the aggregation of select strains of the several species into one product is an application of that newly discovered natural principle [that the strains were noninhibitive]. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. Each of the species of root nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided, and act quite independently of any effort of the patentee.

Stated more succinctly, the Court held that the patent covered nothing more than a discovery of the natural properties of the six bacterium strands; thus, the patent did not constitute a sufficient application of a fundamental principle as envisioned under section 101. Although this case dealt with a product patent, the Court in *Gottschalk v. Benson* rationed that “the same principle applies” to process patents as well.

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39 Funk Bros., 333 U.S. 127 (1948).
40 Id. at 131
Despite the categorical exclusion of these fundamental principles, many of these principles remain undefined by the Supreme Court, leaving lower courts with little or no guidance. In Research Corp. v. Microsoft, Judge Rader observed that, as the Supreme Court had never provided a definition of an “abstract idea,” the Federal Circuit would not “presume to define ‘abstract’ beyond the recognition that this disqualifying characteristic should exhibit itself so manifestly.” Scholars have noticed that this approach, which is not unusual for courts when interpreting a categorical exclusion, has and will amount to an “I know it when I see it” test. Because patents deal with monopolistic exclusions that often have important economic consequences, patent law is not a field that should lend itself to such vague tests, and this stands as another example of a current pitfall in determining patent eligibility.

2. EXAMPLES OF PATENTABLE SUBJECT MATTER

The triology of categorical exclusions—laws of nature, physical phenomena, and abstract ideas—basically stand as the only subject matter completely ineligible for patent protection. These concepts aside, 35 U.S.C.S. § 101 lists four types of innovations that have been deemed eligible subject matter for patent protection: process, machine, manufacture, and composition of matter. As previously stated, this list was intended to be broadly interpreted to include anything made by man, reasoned by the courts to exclude only those things that have been made by nature and merely discovered by man. Remember, even with a broad interpretation of patent-eligible subject matter, the Court has consistently ruled that certain fundamental principles of nature and abstract ideas lie outside the scope of section 101. However, while these principles themselves lie outside the scope of section 101, new and useful applications of these principles can be patented because they merely foreclose on the particular application of that principle, not on the

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42 Research Corp. Techs., Inc. v. Microsoft Corp., 627 F. 3d 859, 868 (Fed. Cir. 2010).
principle itself.

For example, *Diamond v. Diehr* involved the application of the Arrhenius mathematical equation to a process used to mold and cure products made out of synthetic rubber.\(^{44}\) The Court made it clear that a scientific truth, or the mathematical expression of it, is not a patentable invention but that a novel and useful structure created with the aid of that scientific truth, or a process that applies the law of nature or mathematical formula to a known structure “may well be deserving of patent protection.”\(^{45}\) The Court held that while Arrhenius’ equation for calculating the cure time in rubber molding presses is not patentable in isolation, “when a process for curing rubber is devised which incorporates it in a more efficient solution of the equation, that process is at the very least not barred at the threshold by § 101.”\(^{46}\) One important element the Court went to lengths to note is that a distinction arises between those claims that “seek to pre-empt the use of” a fundamental principle, on the one hand, and claims that seek only to foreclose others from a particular “application” of that fundamental principle, on the other.\(^{47}\) This reasoning demonstrates that as long as a patent on a process, machine, manufacture, or composition of matter simply applies a fundamental principle as opposed to foreclosing on the principle itself, substantially pre-empting all uses of that fundamental principle, the patent should qualify under § 101. The Court in *Prometheus* utilized this exact rationale to invalidate the medical diagnosis process patent at issue.

Even though section 101 lists the categories that are eligible subject matter, what actually falls under each category is subject to constant change as technology progresses. This progression of technology and understanding is demonstrated by the recent decisions on

\(^{44}\) *Diehr*, 450 U.S. 175 (1981).
\(^{45}\) Id. at 187.
\(^{46}\) Id. at 188. (italics removed).
\(^{47}\) Id. at 187.
“business methods.” Less than fifteen years ago, business methods were initially deemed completely ineligible subject matter in State Street Bank & Trust Co. v. Signature Financial Group.\textsuperscript{48} Twelve years later, however, the Court in Bilski, the same case which gave rise to the rehearing of Prometheus, specifically overruled State Street, mandating that a business method could be eligible for patent protection as process patents, assuming it met the other requirements to be a patent.\textsuperscript{49} As technology evolves, so too must the understanding of patent eligibility. What once may have been patentable might in the future be viewed as nothing more than a realization of a fundamental principle as our knowledge of that principle grows. In contrast, what once was not eligible under the Patent Act, such as business methods, may well become eligible as we progress.\textsuperscript{50}

Notwithstanding the broad interpretation of §101, the Court has ruled that several fundamental and natural principles lie outside the scope of patentable subject matter. For this reason, a grey area continues to exist in the law such that the issue of patent-eligible subject matter must generally be decided on a case-by-case basis. This uncertainty is exacerbated in the case of process patents because they tend to resemble and are often interpreted as abstract ideas that tie together other potentially patented or patentable innovations thereby forming a new invention.\textsuperscript{51} It is for this reason that the Court should have provided guidelines in Prometheus, either by explaining the current standing of the machine-or-transformation test or by providing new factors to explore.

\textsuperscript{48} State Street, 149 F.3d 1368 (Fed. Cir. 1998).
\textsuperscript{49} See Bilski, 130 S. Ct. 3218 (2010).
\textsuperscript{50} Id.
\textsuperscript{51} See C. Bohannan & H. Hovenkamp, Creation without Restraint: Promoting Liberty and Rivalry in Innovation 112 (2012). (“One problem with [process] patents is that the more abstractly their claims are stated, the more difficult it is to determine precisely what they cover. They risk being applied to a wide range of situations that were not anticipated by the patentee.”).
PART II. THE MACHINE-OR-TRANSFORMATION TEST

The text of the Patent Act does not on its face give much guidance about what constitutes a patentable process. 35 U.S.C.S. 100 (b) defines a process as a “process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.” The Supreme Court has noted that this vague definition is not especially helpful, given that it also uses the term “process” and is therefore somewhat circular. This circular definition leaves unanswered what is actually to be included in the scope of a patentable process. Processes further complicate the issue because they often involve the application of at least one of the trilogy of categorically excluded fundamental principles. Thus, in order to determine if the claimed process restricts itself enough so as to only encompass actual applications of those laws of nature, many lower courts turned to Supreme Court jurisprudence in the development of categorical factors or tests to apply. The most notable and versatile of these tests is the machine-or-transformation test. The roots of the machine-or-transformation test date back to the *Gottschalk v. Benson* decision of 1972.52 Although the Supreme Court consistently applied components of the test for nearly four decades, the test reached its pinnacle of authority as “the” test for process patent eligibility in the Federal Circuit’s 2008 decision of *In re Bilski*. This pinnacle of authority was short-lived as the test was downgraded to a “useful clue” when *Bilski* reached the Supreme Court and its viability left in question after its decision in *Prometheus*.

A. FORMATION OF THE MACHINE-OR-TRANSFORMATION TEST

In the 1972 decision of *Gottschalk v. Benson*, the Supreme Court first began to enunciate what would become the machine-or-transformation test for process patents.53 Drawing on its decision in *Funk Bros.*, the Court reasoned that the same principles in determining the eligibility

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53 *Id.*
of a product claim that deals with the trilogy of categorical exclusions should also apply to process claims. The Court then looked to precedent in order to determine how to apply this principle to process patents, sorting these patents into 1) processes which are attached to a machine or apparatus and 2) those which are not. The Court noted that a process attached to a particular machine could qualify as a precise application of an abstract idea such that it would be eligible subject matter under section 101. It further stated that it could not be disputed that “a process may be patentable, irrespective of the particular form of the instrumentalities used.”

Tailoring its decision to the patent at issue, the Court ruled that “[t]ransformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular machines.” Despite laying down this seemingly hard and fast rule, the Court remained hesitant to establish this clue as the definitive standard for determining process patents. Accordingly, the Justices cautioned that they did not and would not hold that “no process patent could ever qualify if it did not meet the requirements” of being attached to a machine or operating to change articles or materials to a different state or thing.

Notwithstanding its hesitancy to establish a standard for process patents, the Court admitted in Parker v. Flook (Flook) that “this Court has only recognized a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a different state of things.” The Court reaffirmed the applicability of the machine-or-transformation test in Diehr and set forth further qualifications to process eligibility. To be eligible under Diehr, a process must not only satisfy the machine-or-transformation components of the test, but it must also not pre-empt the use of the fundamental principle, i.e. the process

54 Id. at 67.
55 Id. at 71.
56 Id. at 69.
57 Id. at 70.
58 Id. at 71.
must be limited to a particular application of that principle.

B. **The Federal Circuit in Bilski**

In the case of *In re Bilski*, the Federal Circuit (Circuit) noted that the question of process eligibility presented post-*Diehr* asks whether the “[a]pplicants’ claim recites a fundamental principle and, if so, whether it would pre-empt substantially all uses of that fundamental principle if allowed [to stand]”\(^{60}\) The Circuit noted that this is a particularly difficult question to answer given that claims of the twenty-first century are seldom so clearly limited in scope as those in *Gottschalk* or *Diehr*.\(^{61}\) To properly answer this question, it then turned to the machine-or-transformation test, explaining that a “claimed process is surely patent-eligible under §101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”\(^{62}\) According to the Circuit, this test effectively ensures that the process would not pre-empt uses of the principle “that do not also use the specified machine or apparatus in the manner claimed” (prong 1) or uses “to transform any other article, to transform the same article but in a manner not covered by the claim, or to do anything other than transform the specified article” (prong 2).\(^{63}\) After the machine or transformation that limits the process to a particular application of the natural phenomenon is identified under one of these prongs, the Circuit required that the claim pass two additional considerations to ensure that the scope of the process is limited to that specific application. First, the use of a specific machine or

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\(^{60}\) *In re Bilski*, 545 F. 3d at 954

\(^{61}\) Id.

\(^{62}\) Id. at 954; *See Benson*, 409 U.S. at 70 (“Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines.”); *Diehr*, 450 U.S. at 192 (holding that use of mathematical formula in process "transforming or reducing an article to a different state or thing" constitutes patent-eligible subject matter); *see also Flook*, 437 U.S. at 589 n.9 (“An argument can be made [that the Supreme] Court has only recognized a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a 'different state or thing'”); *Cochrane v. Deener*, 94 U.S. 780, 788, 1877 Dec. Comm'r Pat. 242 (1876) (“A process is . . . an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.”).

\(^{63}\) *In re Bilski*, 545 F.3d at 954.
transformation of an article “must impose meaningful limits on the claim's scope to impart patent-eligibility.”\textsuperscript{64} Second, the involvement of the machine or transformation in the claimed process “must not merely be insignificant extra-solution activity.”\textsuperscript{65} Thus, to satisfy the transformative branch, “the transformation [in question] must be central to the purpose of the claimed process.”\textsuperscript{66}

The Circuit elevated the importance of the machine-or-transformation test as the test for process patents by noting that transformation is the clue for patentability.\textsuperscript{67} In the same action, the Circuit rejected the applicability of the “physical limitations” test as insufficient for a § 101 determination. Therefore, “the proper inquiry under § 101 is not whether the process claim recites sufficient ‘physical steps,’ but rather whether the claim meets the machine-or-transformation test.”\textsuperscript{68} As a result, “even a claim that recites ‘physical steps’ but neither recites a particular machine or apparatus, nor transforms any article into a different state or thing, is not drawn to patent-eligible subject matter. Conversely, a claim that purportedly lacks any ‘physical steps’ but is still tied to a machine or achieves an eligible transformation passes muster under § 101.”\textsuperscript{69}

C. \textsc{Bilski} and the \textsc{Supreme Court}: A Useful Factor

The machine-or-transformation test remained the sole test for only a very brief period because the Supreme Court wasted no time unanimously voting to overturn the Circuit’s decision. The Court did show high regard for the Circuit’s thorough and insightful opinion,

\textsuperscript{64} Id. at 691.
\textsuperscript{65} Id. at 692.
\textsuperscript{66} Id. (emphasis added).
\textsuperscript{67} See \textit{In re Bilski}, 593 F. 3d at 966, n. 11 (“We believe that the Supreme Court spoke of the machine-or-transformation test as the “clue” to patent-eligibility because the test is the tool used to determine whether a claim is drawn to a statutory “process”—the statute does not itself explicitly mention machine implementation or transformation. We do not consider the word “clue” to indicate that the machine-or-transformation test is optional or merely advisory. Rather, the Court described it as the clue, not merely “a” clue.”) (emphasis added).
\textsuperscript{68} Id. at 961.
\textsuperscript{69} Id.
noting that students of patent law would be well advised to study these scholarly opinions.\textsuperscript{70} Furthermore, although a unanimous decision to overturn the Federal Circuit, the Supreme Court’s \textit{Bilski} decision consists of three concurring opinions on the applicability of the machine-or-transformation test to process patents. Justice Kennedy delivered the opinion of the Court except for sections II-B-2 and II-C-2, the sections expounding on the test’s scope and function. The general consensus of the Court, mirrored by the brief summary-concurrence of Justice Breyer, is that the machine-or-transformation test remains a useful tool in the discussion of patent eligibility; however, all of the Justices agree that it cannot stand as the \textit{sole} factor for eligibility. Because the Court failed to reach a consensus in \textit{Bilski}, the application of the machine-or-transformation test remains uncertain to this day.

1. \textsc{Justice Kennedy’s opinion, joined by Chief Justice Roberts and Justices Thomas and Alito}

Justice Kennedy demonstrates an air of judicial restraint for applying categorical tests, explaining that a “categorical rule denying patent protection for inventions in areas not contemplated by Congress . . . would frustrate the purposes of the patent law.” The opinion concedes that the test may well provide a sufficient basis for evaluating processes of the Industrial Age because many of those inventions are grounded in a physical or other tangible form.\textsuperscript{71} However, technology has progressed past this stage and proposed new issues such as “software, \textit{advanced diagnostic medicine techniques}, and inventions based on linear programing, data compression and the manipulation of digital signals” that would not be considered under the test.\textsuperscript{72} For this reason, Justice Kennedy proposes that it would not make sense to “require courts

\textsuperscript{70} \textit{Bilski}, 130 S. Ct. at 3224.

\textsuperscript{71} \textit{Id.} at 3227.

\textsuperscript{72} \textit{Id.} (emphasis added). It is important to note that \textit{Prometheus} was pending on certiorari at the time \textit{Bilski} was decided. Although advanced diagnostic medicine techniques, the subject of the \textit{Prometheus} decision, was specifically listed in the examples of Information Age technology that throw a wrench into the applicability of the
to confine themselves” to the questions posed by the test. While not a categorical rule, the test does remain useful. The opinion summarized the test’s current role:

This Court’s precedents establish that the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101. The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible “process.”

Justice Kennedy further noted that patent law in the Information Age faces a great challenge “in striking the balance between protecting inventors and not granting monopolies over procedures that others would discover by independent, creative application of general principles.” Again utilizing restraint, Justice Kennedy refused to partake in any role in this determination, expressing that “[n]othing in this opinion should be read to take a position on where that balance ought to be struck.”

2. Justice Stevens’ Concurrence, Joined by Justices Ginsburg, Breyer, and Sotomayor

Justice Stevens wrote a separate concurrence in an attempt to “restore patent law to its historical and constitutional moorings.” The opinion reflects the belief that the Court correctly held that the machine-or-transformation test is not the sole test for what constitutes a patentable process; rather, it is a “critical clue.” Albeit a critical clue, the test is not and cannot act as the end-all determination for a process patent. Justice Stevens drew particular ire with the Court’s suggestion that any series of steps that is not itself an abstract idea or law of nature may constitute a “process” within the meaning of section 101. Accordingly, he warned that “[e]ven if the machine-or-transformation test may not define the scope of a patentable process, it would be

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machine-or-transformation test, the Court refused to elaborate in Bilski whether such technologies should or should note receive patent protection.

72 Id. at 3227.
73 Id. at 3228.
74 Id.
75 Id. at 3232.
76 Id. at 3232.
77 Id.
a grave mistake to assume that anything with a ‘useful, concrete and tangible result’ may be patented.” On these beliefs, he argued on a historical basis that it would have been wiser to simply rule that business methods are not patentable under section 101 instead of continuing to rely on a potentially inconclusive machine-or-transformation test.

3. **CONCLUSION OF BILSKI**

    Justice Breyer’s concurrence adds little to the discussion of the machine-or-transformation test, but it does provide a decent summary of the Court’s view of the test. Justice Breyer notes the test has repeatedly helped the Court to determine what constitutes a patentable process in the past. However, while the test has been and continues to be a useful and important clue, the Court has never indicated it to be the *sole* test. The test acts as an “important example” of how a court can determine patentability under section 101, not the means of determining the patentability of all processes. To this end, Justice Breyer adopted the same restrictive view proposed by Justice Stevens that not *everything* which produces a useful, concrete, and tangible result should be patentable. Rather, the Court emphasizes that a process claim meets the requirements of § 101 “when, considered as a whole, it is performing a function which the patent laws were designed to protect.” As previously indicated, the transforming or reducing of an article to a different state or thing would act as one example of a function the laws were designed to protect.

    Courts need guidance for process patent determinations under section 101, and the *Bilski* decision failed to hand down this needed guidance. In the end, the nine justices were unable to come to any consensus on how the machine-or-transformation test should be applied. The

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78 *Id.* at 3232 n. 1.
79 *Id.* at 3258.
80 *Id.*
81 *Id.*
82 *Id.*
justices did agree that the test could not function as the sole test for the subject matter eligibility of process claims; however, their opinions differ on the future capacity and applicability of the test. To this day, the future of the machine-or-transformation test remains uncertain. Clearly the test should occupy some place in the determination of patent-eligible process; what that place is will only be discovered through future decisions.

PART III. MAYO V. PROMETHEUS

A. THE PROMETHEUS PATENT

Prometheus Laboratories was the sole and exclusive licensee of U.S. Patent No. 6,355,623 and U.S. Patent No. 6,680,302, the patents at issue in this matter.83 The processes covered by these patents can most simply be described as a method for determining the optimal dosage of thiopurine drugs used to treat gastrointestinal and non-gastrointestinal autoimmune diseases.84 Thiopurine drugs have proven beneficial in the treatment of diseases such as Crohn’s disease and ulcerative colitis as long as they are administered within a specific dosage band that differs for each patient.85 Because the way in which people metabolize thiopurine compounds varies, the same dose of a thiopurine drug affects different people differently, and it has posed great difficulty to doctors in determining “whether for a particular patient a given dose is too high, risking harmful side effects, or too low, and so likely ineffective.”86

The pertinent prior art for this process includes the knowledge “that levels in a patient’s blood of certain metabolites, including, in particular, 6-thioguanine and its nucleotides (6-TG) and 6-methyl-mercaptopurine (6-MMP), were correlated with the likelihood that a particular

83 Prometheus, 132 S. Ct. at 1295.
84 Id.
85 Id.
86 Id.
dosage of a thiopurine drug could cause harm or prove ineffective.”  

However, persons with, or having, ordinary skill in the art did not know the precise correlations between metabolite levels and likely harm or ineffectiveness until the research that led to the filing of these patents was able to identify these correlations with some precision. Specifically, the patents embody the findings that “concentrations in a patient’s blood of 6-TG or of 6-MMP metabolite beyond a certain level (400 and 7000 picomoles per $8 \times 10^8$ red blood cells, respectively) indicate that the dosage is likely too high for the patient,” likely increasing the risk of harmful side effects, while “concentrations in the blood of 6-TG metabolite lower than a certain level (about 230 picomoles per $8 \times 10^8$ red blood cells) indicate that the dosage is likely too low to be effective.”  

The patents themselves were drafted to embody the findings of this research as a set of processes. The Supreme Court and the Federal circuit used claim 1 of the ‘623 patent to be typical of all of the claims at issue. Claim 1 of the ‘623 patent describes one of the claimed processes as follows:

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. 

B. The Path to the Supreme Court

In exercising its license on the ‘623 and ‘302 patents, Prometheus sold diagnostic tests that embodied the processes described therein. For a period of time, Mayo Clinic Rochester and Mayo Collaborative Services (collectively Mayo) bought and used these tests from Prometheus.

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87 Id.
88 Id.
89 See id. (Quoting Patent No. 6,355,623, col. 20, ll. 10-20, 2 App. 16) (spacing omitted).
In 2004, Mayo discontinued its use of the Prometheus tests and began to use its own slightly revamped test that applied minimally different metabolite levels to determine toxicity. Prometheus claimed direct infringement on the ‘623 patent and filed suit.

The District Court found that, given the margin of error allowed in the tests, Mayo’s test numbers were too close to those used in the Prometheus test. For this reason, the Court reasoned that a doctor using Mayo’s test could violate the patent even if he did not actually alter his treatment decisions in light of the test. Accordingly, it decided that the Mayo test infringed upon claim 7 of the ‘623 patent. Nonetheless, the District Court granted Summary Judgment in favor of Mayo, finding that the process effectively claimed non-patentable natural laws or natural phenomena—namely the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages.

On appeal, the Federal Circuit reversed the summary judgment in Prometheus I. The Circuit looked to the additional steps of the claimed process which involved the transformation of the human body or of blood taken from the body. Thus, the Circuit ultimately ruled that the patents satisfied the Circuit’s machine-or-transformation test, which the Circuit thought sufficient to “confine the patent monopoly within [the] rather definite bounds” required to satisfy section 101; i.e. the process did not preclude on a law of nature.

Following the Federal Circuit’s decision, Mayo filed a petition for certiori to the Supreme Court. At the time of Prometheus I, the Supreme Court was considering its decision in Bilski that concerned the scope and applicability of the machine-or-transformation test. While the petition for certiori was pending, the Court handed down its Bilski decision, holding that the

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90 Id. at 1296.
91 Id. at 1295.
92 Id. at 1296.
93 Id.
94 Id.
machine-or-transformation test was only an important and useful clue, not the definitive test of patent eligibility. The Court granted Mayo’s petition, vacated the Federal Circuit’s decision, and remanded the case to be reexamined in light of Bilski.

On remand in Prometheus II, the Federal Circuit reaffirmed its prior ruling of patent eligibility. It thought that even with the machine-or-transformation test merely acting as an important and useful clue, the application of the test led to a “clear and convincing conclusion” that the claimed processes did not encompass laws of nature or preempt natural correlations. Mayo filed another petition for certiori to review the Federal Circuit’s decision, and the Supreme Court once again granted the petition to determine the eligibility of the patent.

C. PROMETHEUS FALLS SHORT AT THE SUPREME COURT

After more than three years of arguments throughout the court system, Prometheus found itself before the Supreme Court for the second time. This time the Court would hear the case. In his unanimous opinion for the Court, Justice Breyer precisely stated the question before the Court as to whether the “patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws.” On March 20, 2012, the Supreme Court handed down its decision. “No,” the claims did not restrict the applications enough to render them patentable applications of natural laws. Mayo’s motion for summary judgment was granted and the patent was ruled ineligible. How the Court reached its decision is of particular importance because the decision barely mentions the machine-or-transformation test. Particularly, the Court referred to prior case law to make its

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95 Id.
96 Id.
97 Id.
98 Id.
99 Id. at 1297.
100 Id.
ruling, silently inferring that lower courts should do the same instead of looking for categorical tests.

1. Dissecting the Claimed Process

The largest concern in this case, and in most process patent cases, is that patent law should not inhibit further discovery by improperly tying up the future use of laws of nature. Indeed, a claimed process can apply a natural law as long as that application is adequately limited to foster future development and discovery. To analyze the patent’s built-in restrictions, the Court broke the claimed process up into three distinct parts—an “administering” step, a “determining” step, and a “wherein” step.\(^{101}\) Although the Court admitted that these steps did not embody laws of nature themselves, the justices ultimately reasoned that they were insufficient to transform the nature of the claim to allow the patent’s eligibility.

The administering step attempts to limit the patent by referring to the relevant, pre-existing audience of doctors that administer thiopurine drugs.\(^{102}\) Citing *Bilski*, the Court reasoned that this does not constitute an adequate limitation because “the prohibition against patenting abstract ideas ‘cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.’”\(^{103}\) The “wherein” step merely advises the relevant audience (doctors) about the applied laws of nature, leaving it to the doctors to actually apply those laws appropriately where they are relevant.\(^{104}\) The Court analogizes this step to Einstein explaining his basic laws of relativity to linear accelerator operators and then “trusting them to use it where relevant.”\(^{105}\) The “determining” step carries a little more weight as it directs the

\(^{101}\) Id.
\(^{102}\) Id.
\(^{103}\) Id.
\(^{104}\) Id.
\(^{105}\) Id.
doctor to determine the level of relevant metabolites. However, the claim opens itself to whatever process the doctor or laboratory wishes to use in this determination, including those in the prior art. Thus, this step simply tells doctors “to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field.” The Court found each of the steps insufficient on its own to transform a non-patentable law of nature into a patent-eligible application of such a law. Furthermore, even with the three sets of limitations taken together, the combination of the steps also do not constitute a new patentable combination as it amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.

2. The Flook-Diehr Spectrum

The Court then turned to precedent, establishing a spectrum for patent eligibility in order to support its decision. The Diehr process stood on one end of the spectrum, representing that which was deemed patent eligible under section 101. As illustrated in Part I, the Diehr process constituted a patentable application of a natural law—the Arrhenius equation—to cure and mold rubber products because “the way the additional steps of the process integrated the equation into the process as a whole.” The claim in that case did not seek to pre-empt the use of the equation, but only to foreclose the use of that equation in conjunction with all the other steps in the process. Thus, this limitation in the claim transformed the process into a truly inventive application of the formula, patentable under section 101.

Flook stands on the opposite end of the spectrum as an example of a patent-ineligible process. Much like Diehr, the process in Flook involved a basic mathematical equation that

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106 Id.
107 Id. at 1298.
108 Id.
109 Id.
would not be patentable alone.\textsuperscript{110} This mathematical equation was at the center of a method used to adjust alarm limits in the catalytic conversion of hydrocarbons. Unlike the \textit{Diehr} process, however, the \textit{Flook} process did not “explain how the variables used in the formula were to be selected, nor did the [claim] contain any disclosure relating to chemical processes at work or the means of setting off an alarm or adjusting the alarm limit.”\textsuperscript{111} Thus, the \textit{Flook} claim was not patentable because it lacked the requisite limitations to restrict it to a particular application.\textsuperscript{112}

With the spectrum set up, the Court determined where the \textit{Prometheus} patent would sit on the spectrum. The Court reiterated that all the claim does is simply tell doctors to:

(1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law.\textsuperscript{113}

The Court found the claim to be characterized roughly in the same manner as the claim in \textit{Flook}.\textsuperscript{114} The Court ultimately placed \textit{Prometheus} on the side of ineligibility, weaker than the claim in \textit{Diehr} and no stronger than the claim in \textit{Flook}.

\textbf{Part IV. Analysis}

\textbf{A. SCOPE OF THE DECISION}

Clearly, the \textit{Prometheus} decision has direct consequences for both Prometheus Laboratories and Mayo—Prometheus is now the sole licensee of an invalid patent and can no longer force Mayo and other companies to pay the royalties for using the claimed processes. Furthermore, now that companies do not have to pay licensing fees to Prometheus, diagnostic costs should decrease for patients treated with thiopurine drugs, and the number of businesses

\textsuperscript{110} \textit{Id.} at 1299.
\textsuperscript{111} \textit{Id.}
\textsuperscript{112} \textit{Id.}
\textsuperscript{113} \textit{Id.}
\textsuperscript{114} \textit{Id.} at 1300.
offering these diagnostic services should increase. However, Supreme Court decisions rarely, if ever, affect only the parties involved. Realistically, it is not the parties that we concern ourselves with for their fate has been sealed. Nine Justices decided that the Prometheus patent was not valid subject matter—the patent is clearly invalid, and, from a legal standpoint, we have to adjust our views to fit this outcome. Instead, the importance lies in the impact that this decision will have on the future. Supreme Court decisions stand as binding precedent to all courts in the country applying the same law. *Prometheus* is the most recent case to discuss patent-eligible subject matter under § 101; therefore, unless, and until, Congress amends its statutory definition of patentable subject matter, every federal district and circuit court dealing with the eligibility of a process patent must base its decision in light of the *Prometheus* reasoning. Because this case did not supplement the law with categorical standards to apply, courts, patent attorneys, and patent examiners are going to remain uncertain how they should analyze these patents in the future.

The decision has the potential to transcend beyond patent law, particularly in the way that medical research will be funded and conducted in the future. Prometheus and several *amici* urged the Court to realize that research—not just research on medical treatments—is extremely expensive. Prometheus estimated that bringing a single diagnostic product to market could cost $10-100 million after heavy investments in research and pre-market trials.\(^{115}\) A company cannot afford to give away such a heavy investment without recuperating its losses. If strong patent protection is not given as incentive for taking the discovery public, more companies will begin to take the steps necessary to maintain trade secrets. A switch to trade secrets or product patents would stifle innovation much more than a twenty-year patent ever could. Remember, even if a

process patent were to foreclose on some applications of a natural law, continued research can be conducted on those principles, and the “new and useful improvements” thereupon could be the subject of a new patent.\textsuperscript{116} Trade secrets, on the other hand, would compel companies to indefinitely keep the information from reaching any outsiders, let alone the public at large. The entire purpose of the Patent Act is to incentivize creativity and the eventual dissemination of ideas to the public domain. Indeed, applications for patents are published and accessible by anyone with an Internet connection or a local law library near by. Essentially, the protective incentive precludes others by law from using and infringing upon the patent, but the idea enters the prior art nonetheless.

The Court seems to have thought otherwise, finding that the invention in \textit{Prometheus} did not provide the public with enough benefit to warrant the incentive of patent protection. The Court sided with the \textit{amici} of medical associations and doctors—the groups normally forced to pay licensing fees on such patents—that such processes cannot be patented. Now, companies are faced with two economic realities: 1) continue to conduct expensive research but keep the information from the public as a trade secret in order to recuperate expenses, or 2) cut funding to research in order to remain in business.

4. \textsc{The Machine-or-Transformation Test’s Demise?}

1. A Doubtful Future

For a while, those involved in the fields of patent law and medical diagnostics believed the Supreme Court would use \textit{Prometheus} to clearly elaborate on its stance on the machine-or-transformation test left unanswered by \textit{Bilski}. It would have made sense for the Supreme Court to do so—after all, the Court had just remanded the case to be decided in light of its \textit{Bilski} decision to downplay the importance of the test, and the Federal Circuit responded by continuing

to find clear and compelling eligibility through the test. The first sign that this would not be the case should have come when Supreme Court granted certiorari to determine what seems to be a rather Mayo-friendly question—“Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve ‘transformations’ of body chemistry.”

Unfortunately, no clear guidance was to be surmised from the case, only backhanded inferences on the test’s deficiencies. The Court deliberately turned to comparisons of precedent, not the machine-or-transformation test or any other categorical standard, in order to determine patent ineligibility for the Prometheus claims. Justice Breyer noted that in describing the test as an “important and useful clue” to patentability in the past, the Court “neither said nor implied that the test trumps the ‘law of nature’ exclusion.” However, the test was never intended to trump the law of nature exclusion; rather it was designed to be a useful tool in determining if the claimed process was adequately limited such that the exclusion did not apply. The Federal Circuit viewed the claims as patentable under section 101 because they involved transforming the human body by administering a thiopurine drug and transforming the blood by analyzing it to determine metabolite levels. The Supreme Court shot down this transformation as “irrelevant” because the second step could be satisfied without transforming the blood if science should ever “develop a totally different system for determining metabolite levels that did not involve such a transformation.”

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117 Petition for Writ of Certiorari, Prometheus, 132 S. Ct. 1289 (No. 10-1150).
118 Prometheus, 132 S. Ct. at 1303.
119 Id.
indicates that one might even be feasible, the Court feared that too much future innovation would be foreclosed relative to the contribution of the inventor.

Restricted to the scientific techniques available today, the claimed process undeniably involves a transformation in order to determine the proper adjustment of thiopurine doses. In this regard, the Federal Circuit would have been correct that the patent would survive under the traditional notions of the machine-or-transformation test. However, the Supreme Court went out of its way to once again downgrade the applicability of the test, holding the transformation irrelevant because it could conceivably be bypassed by future discoveries. For this reason, the future of the machine-or-transformation test, or at least its transformation component, remains in doubt.

2. THE NEED FOR GUIDELINES

Courts used the machine-or-transformation test to ensure that a claim that utilized a fundamental principle was adequately limited to a particular application of that principle. Arguably, the Supreme Court should not reestablish the machine-or-transformation test as the sole test for process eligibility because the test unnecessarily limits the eligibility of process patents. The Court has been clear in the past to demonstrate that certain emerging technologies, such as computer programming, would likely fail the test and remain potentially patentable subject matter. However, the Court in *Prometheus* took the exact opposite route, ruling that a claim that fit well into the network of the machine-or-transformation test was nonetheless ineligible for patent protection because it was not a limited application of a fundamental principle. Furthermore, the fact remains that the Court’s decisions in *Bilski* and *Prometheus* have left a void when it comes to understanding patentable subject matter. The Court admits that “[c]ourts and judges are not institutionally well suited to making the kinds of judgments needed
to distinguish among different laws of nature.” As students of the law, judges are not necessarily well versed in the realm of physical science. Patent examiners and patent attorneys, on the other hand, are required to have backgrounds in the sciences to better understand the issues covered by patents. Thus, examiners and patent attorneys are those best suited to make these kinds of judgments; however, they must make these judgments based on the guidelines provided by Court precedent.

The Court had the chance in *Prometheus* to provide that much-needed guidance. Instead, the Court erred on the side of caution believing that a categorical standard or test could grant patent protection to a process that would impermissibly inhibit future innovation premised upon the same natural laws. For this reason, the Court returned to historic roots instead of elaborating on any tests. Now, patent examiners and attorneys are restricted to a historical analysis argument in order to determine patent eligibility, despite having an understanding of the science involved. Thus, in the end, a useful test was stripped of its most basic function, and the patent world is left guessing on how to determine if a process is patent eligible under § 101.

3. THE ISSUE HAS ALREADY EMERGED

2012 can be captioned as the year of “Health Care” for the Supreme Court. Less than two weeks after the Court seemingly stripped the machine-or-transformation test of its final utility in *Prometheus*, the Court heard arguments on the nation’s proposed health care system, coined “Obama-care” by the media. Also, within a week of the *Prometheus* decision, the Court overturned another medical patent in *Association for Molecular Pathology v. Myriad Genetics* and remanded the matter to the Federal Circuit to be decided in light of its *Prometheus* decision.120 The *Myriad* case involved patents of two genes linked to causing breast and ovarian cancer. The purpose of these particular genes is to aid in testing for the known mutations that

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often lead to these forms of cancer. The *Prometheus* decision is not really controlling on the *Myriad* patents. *Prometheus* dealt with a process or method of correlating certain metabolites in the blood with the patient’s health through some unspecified scientific process. The claims on petition for *certiorari* in *Myriad*, on the other hand, have nothing to do with technology or an attempt to apply a law of nature. *Myriad* deals with the patentability of isolated DNA fragments, essentially compositions of matter.\(^\text{121}\) Admittedly, the claims in *Myriad* could be struck down as a discovery of nature or a physical phenomenon, but that is outside the scope of this paper.

4. FACTORS ARE THE ANSWER, NOT TESTS

Clearly, industries, particularly medical science industries, are making great technological leaps. As discussed, patent law aims to strike a balance between two competing and compelling interests: 1) the dissemination of ideas to the public domain so that future research and discovery can transpire, and 2) rewarding those whose resources, time, and creativity made the innovation and who disclosed the information to the public. The recent cases of *Prometheus*, *Bilski*, and possibly *Myriad*, mark a departure from the true balance posed by the system. Essentially, these cases have removed the reward given to invention in favor of immediate dissemination of these principles into the public domain.

If this balance becomes too skewed, companies will lose faith in the patent system and turn to trade secrets to protect their investments. Certain guidelines must be mandated in the dissection of patent claims to ensure that this departure from patent favorability does not occur. The Supreme Court has admitted that it and other courts are not the proper vessel for establishing tests or factors because they are judges, not scientists or other persons having ordinary skill in the art. Instead, such provisions must be proposed and signed into law by Congress under the tutelage of those who are skilled in the arts.

\(^{121}\) *Id.*
Technology is currently progressing too quickly for black letter tests to be regularly applied. Instead, Congress should propose a list of factors drawn from Court precedent and Congressional intent to be used in dissecting patents that claim applications of fundamental principles. Among these factors, the machine-or-transformation test could remain useful in the capacity the Court originally intended it to fill. With no one factor dispositive of patent eligibility or ineligibility, courts would be able to use a totality of the circumstances to decide if a patent’s claims are adequately limited to encompass patentable applications of these principles. Thus, a dispositive list of factors would provide both the guidelines needed by the patent world today along with the flexibility required as technology progresses.

**Conclusion**

Patents are designed to grant a limited monopolistic right to incentivize the dissemination of an invention to the public. Realizing that not every idea deserves such protection, Congress limited patents to certain subject matter. The patent world has been left guessing for the past few years as to how it should analyze process patents that claim an application of a fundamental principle. Ultimately, *Prometheus* did not live up to its namesake and provide the much needed guidance by the Court. The case offered no “fire,” no clarity, to the eligibility of process patents. To this day, a certain sense of ambiguity continues to cloud the way a process patent should be scrutinized. Unfortunately, it is unclear when, if ever, such guidelines will come from either Congress or the Supreme Court.