The Double-Edged Sword of Patent Protection: How Courts Wielding the Subject Matter Exclusion Doctrine May Slash the Development of Personalized Medicine Technology

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I. Introduction

Personalized medicine holds great promise for improving the diagnosis, treatment, and management of diseases such as cancer. Personalized cancer therapies rely on the detection and measurement of biomarkers for the diagnosis or treatment of an individual. The presence of certain biomarkers, for example, may indicate an increased susceptibility to certain forms of cancer. Information from biomarkers may also be used to optimize patient treatment. With personalized cancer therapy, the levels of biomarkers in a patient can be used to determine how well the patient is responding to a course of treatment, whether the dosage of the patient’s...

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1 See Biomarker Definition, NATIONAL CANCER INSTITUTE DICTIONARY OF CANCER TERMS, http://www.cancer.gov/dictionary?cdrid=45618 (last visited Apr. 14, 2014). A biomarker is “[a] biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition.” Id. For further discussion on biomarkers used in clinical applications, see, e.g., Ignacio I. Wistuba et. al., Methodological and practical challenges for personalized cancer therapies, 8 NAT. REV. CLIN. ONCOL. 135, 136 (2011).


3 Treatment of cancer may be improved by knowledge of an individual patient’s molecular characteristics. See Wistuba, supra note 1, at 135. Although chemotherapeutic drugs have been widely used in cancer therapy during the past few decades, research has revealed that most human tumors are heterogeneous. Id. Thus, a “one size fits all” drug regimen for patients with the same tumor type may not be optimal. Id.
medication should be adjusted, or the likelihood of the patient to experience side effects from the
treatment. Also, certain diseased states have been correlated with specific gene expression
profiles, protein levels, or metabolite levels, so detecting these “signature profiles” in a patient
could further inform physicians of the progression of the patient’s disease.

Although new technologies in personalized medicine hold great promise to be highly
effective in disease treatment and management, several challenges inhibit their advancement and
widespread use. One challenge is the economics and cost-effectiveness of their use in disease
treatment. Because some of these technologies are not yet fully developed, the tests may be
unreliable and many health insurance providers are unwilling to cover the costs of using the
tests. But as the reliability of these technologies improves, they are expected to become cost
effective. Another challenge, however, that may hinder further development of personalized
medicine is the increasing risk that biomarker related technology will not receive patent
protection.

Recent Supreme Court (“Court”) decisions indicate that biomarker related technology
will be less likely to receive patent protection because it may be considered patent ineligible
subject matter. Part II of this paper provides an overview of the law on patent subject matter
eligibility and the judicial doctrine of subject matter exclusion. Part II also discusses how the
Court determined patent eligibility of biomarker related technologies in its recent decisions in
Prometheus and Myriad. Next, Part III describes problems with how the Court has applied the

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4 See Jerel Davis, Philip Ma, & Saumya Sutaria, The microeconomics of personalized medicine, McKinsey & Company (February 2010), http://www.mckinsey.com/insights/health_systems_and_services/the_microeconomics_of/personalized_medicine (discussing economic challenges to the advancement of personalized medicine).
5 Id.
6 For an overview of the law on patent subject matter eligibility, see infra notes 11-49 and accompanying text.
7 For a discussion of how the Court determined patent eligibility in Prometheus and Myriad, see infra notes 37-49 and accompanying text.
subject matter exclusion doctrine. Part III argues that when applying the doctrine to determine patent eligibility of an invention, the Court has focused largely on the form of the invention because this is the only practicable way to apply the doctrine. Next, Part IV suggests alternative approaches to determining patent eligibility that avoid the pitfalls of applying the subject matter exclusion doctrine. Finally, Part V concludes that any benefits of having the subject matter exclusion doctrine are outweighed by the dangers of having an inconsistent patent eligibility standard, which will likely ward off investment into new technologies, particularly technologies related to biomarkers or personalized medicine.

II. Subject Matter Eligibility and the Judicial Doctrine of Subject Matter Exclusion

The patent system in the United States was created to incentivize development and innovation in science and technology. To promote development of new technologies, the patent system grants an inventor a limited monopoly on an invention in exchange for public disclosure of the invention. The patent statutes set out various criteria necessary for an inventor to receive a patent on an invention, such as novelty, non-obviousness, and subject matter eligibility of the invention.

Part A of this section discusses the judicial doctrine of subject matter exclusion. Part B discusses how the Supreme Court has applied the subject matter exclusion doctrine to

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8 For a discussion of problems with the Court’s application of the subject matter exclusion doctrine, see infra notes 50-57 and accompanying text.
9 For a discussion of alternative approaches to determining subject matter eligibility, see infra notes 58-62 and accompanying text.
10 For a discussion on the dangers of having inconsistent patent eligibility standards, see infra notes 63-67 and accompanying text.
11 The patent system has its basis in the U.S. Constitution. See U.S. CONST. art. I, § 8 (“Congress shall have the power to . . . promote the progress of science and useful arts, by securing for limited times to . . . inventors . . . the exclusive right to their . . . discoveries”).
13 For a discussion of the subject matter exclusion doctrine, see infra notes 16-19 and accompanying text.
determine patent eligibility of process inventions and biotechnological inventions.\(^{14}\) Finally, Part C discusses the Court’s determination of patent eligibility of biomarker related technology in *Prometheus* and *Myriad*.\(^{15}\)

A. Subject Matter Exclusion Doctrine

Subject matter eligible for patent protection is very broad.\(^{16}\) Over the years, however, the Supreme Court has carved out subject matter to be excluded from patent protection. Under the subject matter exclusion doctrine, laws of nature, naturally occurring phenomena, and abstract ideas are not patent eligible.\(^{17}\) A natural phenomenon like the rising of the sun, for example, cannot be patented. Likewise, laws of nature, such as Newton’s laws of motion or Einstein’s law of mass-energy equivalence, cannot be patented. On the other hand, applications of laws of nature, such as an engine or rocket designed using the laws of physics, may be patent eligible.

The Court has offered at least two justifications for these exceptions. A naturally occurring phenomenon cannot be patented because it is not something a human created or invented and it has always been freely available to all persons.\(^{18}\) Laws of nature cannot be

\(^{14}\) For a discussion of how the Court has determined the patent eligibility of process inventions and biotechnological inventions, see infra notes 20-36 and accompanying text.

\(^{15}\) For a discussion of how the Court determined patent eligibility in *Prometheus* and *Myriad*, see infra notes 37-49 and accompanying text.

\(^{16}\) *See* 35 U.S.C. § 101 (“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.”).


\(^{18}\) *See* Funk Brothers, *supra* note 17, at 130 (“Naturally occurring phenomena and laws of nature are “manifestations of. . . nature, free to all men and reserved exclusively to none.”).
patented because of the danger of inhibiting technological progress. The Court feared that “tying up” natural laws would foreclose the development of technologies that could be derived from use of the natural laws.\(^{19}\)

B. How the Court has Applied the Subject Matter Exclusion Doctrine to Determine Patent Eligibility of Process Inventions and Biotechnology

Distinguishing patent eligible applications of laws of nature from patent ineligible laws of nature or naturally occurring phenomena may be relatively straightforward for inventions that have a clearly man-made physical form. New machines or synthetic chemicals, for example, clearly do not exist in nature and have a physical, tangible form. Thus, during the early part of the last century, when many new inventions were machines or synthetic materials, courts likely had little trouble applying the subject matter exclusion doctrine.\(^{20}\)

Later, however, courts began to encounter inventions that conveyed or processed information. Determining the patentability of these types of inventions information soon proved quite difficult.\(^ {21}\) New methods invented for processing information did not have a physical form. To courts, these inventions appeared to be patent ineligible “laws of nature” or “abstract ideas.” Where the Court drew the line between patentable and unpatentable processes using laws of nature or abstract ideas soon became unpredictable.\(^ {22}\)

\(^{19}\) Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S.Ct. 1289, 1292 (2012) (“Rewarding with patents those who discover laws of nature might encourage their discovery. But because those laws and principles are ‘the basic tools of scientific and technological work,’ there is a danger that granting patents that tie up their use will inhibit future innovation”).


\(^{21}\) For a discussion of how the Court analyzed the patent eligibility of process inventions, see infra notes 23-29 and accompanying text.

\(^{22}\) For a discussion of inconsistent decisions regarding the patent eligibility of process inventions, see infra notes 23-29 and accompanying text. See also Michael Risch, Everything is Patentable, 75 TENN. L. REV. 591, 592 (2008) (stating that “due to the lack of clear and rigorous precedential support for limiting patentable subject matter, current patentable subject matter is inconsistent”); Kristen Osenga, Ants, Elephants, Guns, and Statutory Subject Matter, 39 ARIZ. ST. L.J. 1087, 1093-1103 (2007) (describing inconsistent decisions on patentable subject matter).
The Benson-Flook-Diehr trilogy illustrates the unpredictability of the Court’s approach to determining the patent eligibility of process inventions. Each case involved patent claims to methods for algorithmic processes. In these cases, the Court found that equations or algorithms that the processes used were “laws of nature” or “abstract ideas.” The Court explained that although laws of nature or abstract ideas are patent ineligible, their application may be patent eligible, if the application was sufficiently “inventive.”

What exactly made an application of an abstract idea or a law of nature “particular” or “inventive” is unclear. The Court in Benson and Flook found claims to methods involving the application of algorithms or equations patent ineligible. But, surprisingly in Diehr, the Court found a method that applied a well-known equation to calculate the optimal curing time of rubber patent eligible. Some scholars have criticized the distinctions the Court drew between the claims in Flook and Diehr, claiming that the result in both cases should have been the same.

23 In Benson, the patent at issue claimed a method for converting binary-coded decimal digits to pure decimal digits patent ineligible. Benson, supra note 17, at 65. In Flook, the process related to a method for updating alarm limits. Flook, supra note 17, at 585. During the catalytic conversion of hydrocarbons, operating conditions, such as flow rates, temperature or pressure, were constantly monitored, and when any of these process variable exceeded a predetermined value (the “alarm limit”), a signal would be given to warn operators of possible abnormal conditions or danger. Id. During steady-state operation of the reactor, the alarm limits were usually fixed. Id. But, during transient operation (for example, during start up), the alarm limits needed to be updated periodically. Id. The patent-in-suit in Flook claimed a process comprising the following steps: (1) measurement of current value of a chemical process parameter (e.g. the temperature); (2) use of an algorithm to calculate an updated alarm limit, based on the parameter’s current value; and (3) adjustment of the alarm limit to the updated alarm limit. Id. at 585-86. Meanwhile, in Diehr, the claimed process related to a method for “molding raw, uncured synthetic rubber” into “cured precision products.” Diamond v. Diehr, 450 U.S. 175, 177 (1981). The process used a mold to shape the rubber under heat and pressure and then cure the rubber in the mold so that the rubber product would retain its shape and be functionally operative after the molding process was complete. Id. To achieving a perfect cure of the rubber product, the rubber must be placed in the mold at precise temperatures and lengths of time, depending on the thickness of the mold and thickness of the rubber article to be molded. Id. The patent-in-suit claimed a process comprising the following steps: (1) measuring of temperature inside the mold; (2) feeding measured temperature to a computer, which repeatedly recalculates the cure time using the Arrhenius equation; and (3) sending a signal to open the mold press, if the recalculate cure time is equal to the time that has elapsed. Id. at 178-79.

24 See, e.g., Flook, supra note 17, at 589 (“[A]n algorithm, or mathematical formula, is like a law of nature.”).

25 See, e.g., id. at 594 (indicating that application of algorithm or equation must have an “inventive concept” to be patent eligible).

26 See Benson, supra note 17, at 93 (finding method for converting binary-coded decimal digits to pure decimal digits patent ineligible under 35 U.S.C. § 101); Flook, supra note 17, at 594-95 (finding process relating to updating alarm limits during catalytic conversion of hydrocarbons patent ineligible).

because the patents in both cases claimed processes for computing and adjusting temperatures of chemical reactions for the optimal production of a desired substance.\textsuperscript{28} Perhaps the only difference between the processes was that the process in Diehr appeared to involve more “bells and whistles” or “moving parts,” such as the opening and closing of a mold, than the process in Flook.\textsuperscript{29}

Inventions in the biotechnological fields were also at risk of being considered patent ineligible subject matter because many of these inventions comprised of “naturally occurring” elements. Generally, mere human intervention or human design was not sufficient to make an invention with naturally occurring elements patent eligible. In Funk Brothers, the Court found that a specific mixture of bacterial strains to be used as a fertilizer with superior properties was not patent eligible because each strain of bacteria in the mix occurred naturally and the properties of the bacteria in the mix occurred naturally.\textsuperscript{30} Although each of the bacterial strains was naturally occurring, the particular blend itself, which the inventor used as a fertilizer, did not occur in nature. On the other hand, human manipulation of an organism’s genetic material may

\textsuperscript{28} See, e.g., Iver P. Cooper, Process patent eligibility: the “mental steps” doctrine, computer programs, and business methods, 1 BIOTECHNOLOGY AND THE LAW § 3:9 (June 2012) (finding that steps in Diehr process were “quite analogous” to those in Flook process); Andrew L. Schwartz, More Than Just An Algorithm: Reconciling the Necessity For Disaggregating the Business Method, With Bilski’s Abstract Test, THE NATIONAL LAW FORUM, http://nationallawforum.com/2011/04/25/more-than-just-an-algorithm-reconciling-the-necessity-for-disaggregating-the-business-method-with-bilski%E2%80%99s-abstract-test/ (last visited Jan. 5, 2014) (discussing how Diehr decision, which did not overrule Benson and Flook decisions, never resolved “physical component ambiguities” when determining patentability of processes which were “part physical, part algorithm”).

\textsuperscript{29} See Prometheus, supra note 19, at 1298-99 (explaining that the process in Diehr, which involved steps of installing rubber in a mold, closing the press, measuring the temperature of the mold, recalculating the cure time, and opening the mold was “inventive” whereas the process in Flook, which involved only steps of measuring current reaction conditions and calculating updated alarm limits, was not “inventive”).

\textsuperscript{30} Funk Brothers, supra note 17, at 130. The claimed invention in Funk Brothers concerned a mixture of different strains of Rhizobium bacteria used to inoculate seeds of leguminous plants. Id. at 128-29. The ability of the leguminous plants to fix nitrogen depended on the presence of Rhizobium in the plant roots. Id. at 128. No single species of Rhizobium could infect all leguminous plant species, but each species of Rhizobium could infect a particular group of leguminous plant species. Id. at 129. Thus, to fertilize leguminous plants of different species, a farmer typically had to buy separate strains of Rhizobium for each plant species because using a mixture of Rhizobium species often worked poorly due to the inhibiting effect each bacterial strain had on the other. Id. The inventor in Funk Brothers discovered a certain mixture of Rhizobium bacteria in which the different bacterial strains did not exert an inhibiting effect on each other, thus creating a single mixture of Rhizobium that could be used on different leguminous plant strains. Id.
be sufficient to make an organism patent eligible. In *Chakrabarty*, the Court held that a genetically engineered bacterial strain was patent eligible because the engineered bacteria did not occur in nature.\(^{31}\) The bacterial strain in *Chakrabarty* was engineered to metabolize oil by transforming the bacteria with plasmids bearing genes encoding oil-degrading enzymes.\(^{32}\)

In 2008, the Court of Appeals for the Federal Circuit (“CAFC”) in *In re Bilski* attempted to reconcile the Supreme Court’s decisions on subject matter eligibility and concluded that the Court’s past decisions essentially amounted to the “machine or transformation” test.\(^{33}\) Under the test, a process was patent eligible if (1) the claimed process was “tied to a particular machine or apparatus,” or (2) the claimed process “transforms a particular article into a different state or thing.”\(^{34}\) The CAFC has found biomarker related technology patent eligible under this test.\(^{35}\) Not long after, however, the Supreme Court rejected the “machine or transformation” test as a definitive test for patent eligibility.\(^{36}\)

C. How the Court Applied the Subject Matter Exclusion Doctrine in *Prometheus* and *Myriad*

Recently, the Supreme Court revisited the question of subject matter eligibility when it considered the patent eligibility of biomarker related technology in *Prometheus* and *Myriad*. In *Prometheus*, the Court considered the patent eligibility of a process for using levels of biomarkers to optimize the drug dosage of a patient.\(^{37}\) The method relied on the use of

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\(^{31}\) *Chakrabarty*, supra note 17, at 310.

\(^{32}\) *Id.* at 305.

\(^{33}\) *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008).

\(^{34}\) *Id.*


\(^{36}\) See *Prometheus*, *supra* note 19, at 1296 (“[T]he ‘machine or transformation test’ is not a definitive test of patent eligibility, but only an important and useful clue.”) (citing Bilski v. Kappos, 130 S.Ct. 3218 (2010)).

\(^{37}\) The patents-in-suit covered a method for optimizing the therapeutic efficacy of thiopurine drugs used to treat autoimmune disorders. *Prometheus, supra* note 19, at 1294-95. At high concentrations in the body, the drug is toxic, but at low enough concentrations, the drug is therapeutically ineffective. *Id.* at 1295. The optimal drug dose is not the same for all patients because individual patients metabolize the drug differently, and doctors need to be able to determine the right dose to administer to a patient. *Id.* The patents described a method for determining the
correlations between certain biomarker levels in a patient and the likelihood of the drug being effective or toxic to the patient.\textsuperscript{38} Earlier, the CAFC had concluded that the method was patent eligible because the introduction of the drug into a patient “transformed” the patient’s body into a different state and the use of the correlations between biomarker levels and drug efficacy in the claimed method did not preempt all uses of the correlations.\textsuperscript{39}

The Court, however, rejected the CAFC’s conclusion. Instead, when evaluating the patentability of Prometheus’s method of using correlations between biomarker levels and drug efficacy, the Court deemed the correlations to be “laws of nature.”\textsuperscript{40} The Court then cited its decisions \textit{Diehr} and \textit{Flook}, and explained that the proper analysis was to consider whether the application of the laws of nature was “particular” or “inventive” enough to make it patent eligible. The Court’s inquiry then focused on whether Prometheus’s application of the knowledge of the correlations involved “particular, inventive” steps.\textsuperscript{41} The Court found that merely using the correlations to determine the appropriate dosage of a drug for a patient was not sufficiently inventive because the use of the correlations appeared to be straightforward and conventional.\textsuperscript{42} Thus, the Court found the claimed method patent ineligible.\textsuperscript{43}

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\item \textsuperscript{38} Id.
\item \textsuperscript{39} Prometheus, supra note 35, at 1345-49; Prometheus Labs. v. Mayo Collaborative Servs., 628 F.3d 1347, 1356-57 (2010).
\item \textsuperscript{40} See Prometheus, supra note 19, at 1296-98. The Court found the correlations between the metabolite levels in the body and the likelihood of the drug’s ineffective or toxic effect were “natural laws.” Id.
\item \textsuperscript{41} Id. at 1290 (“But to transform an unpatentable law of nature into a patent-eligible application of such a law, a patent must do more than simply state the law of nature while adding the words ‘apply it.’ It must limit its reach to a \textit{particular, inventive} application of the law”) (emphasis added).
\item \textsuperscript{42} See id. at 1298 (discussing why claimed process was not inventive). According to the Court, the additional steps of administering the drug, measuring subsequent levels of the metabolites and then determining whether the amount of drug administered was likely to be toxic or effective based on the levels of metabolites measured were simply steps that were “well-understood, routine, conventional activity previously engaged in by scientists who work in the field.” Id.
\item \textsuperscript{43} Id. at 1298.
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Meanwhile, the Court in *Myriad* considered patent claims relating to breast cancer diagnostic tests.\(^{44}\) The patents at issue in *Myriad* claimed isolated DNA and cDNA encoding human genes with point mutations associated with elevated risk of breast cancer.\(^{45}\) Previously, the CAFC had concluded that isolated DNA was patent eligible because isolated DNA was distinctly different from native DNA in chemical structure.\(^{46}\)

However, the Court in *Myriad* rejected this conclusion. The Court instead relied on its decisions in *Chakrabarty* and *Funk Brothers*, and focused its inquiry into whether the patents claimed subject matter that was naturally occurring or contained naturally occurring elements.\(^{47}\) The Court concluded that mere isolation of DNA was insufficient to make otherwise naturally occurring DNA patent eligible.\(^{48}\) But, cDNA was patentable because the Court deemed it did not naturally occur in human cells.\(^{49}\)

### III. Problems with Applying the Subject Matter Exclusion Doctrine

Overall, the Court’s decisions on subject matter eligibility reflect a tendency to find patent eligibility based on the form of the invention, resulting in a subjective, case-by-case determination of patent eligibility. For example, when considering what is “naturally occurring,” the Court has not set any clear standard. In some cases, human intervention could make an

\(\text{\textsuperscript{44} Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S.Ct. 2107, 2109-10 (2013).}\)
\(\text{\textsuperscript{45} Id.}\)
\(\text{\textsuperscript{46} Ass’n for Molecular Pathology, supra note 35, at 1328-31.}\)
\(\text{\textsuperscript{47} See Myriad, supra note 44, at 2116 (“We must . . . determine whether Myriad's patents claim any ‘new and useful ... composition of matter,’ § 101, or instead claim naturally occurring phenomena.”).}\)
\(\text{\textsuperscript{48} See id. at 2117 (“Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.”).}\)
\(\text{\textsuperscript{49} See id. at 2110 (discussing patentability of cDNA). According to the Court, because cDNA is not a “product of nature,” it is patent eligible. Id. “Its creation results in an exons-only molecule, which is not naturally occurring. Its order of the exons may be dictated by nature, but the lab technician unquestionably creates something new when introns are removed from a DNA sequence to make cDNA.” Id.}\)
invention with “naturally occurring” elements patentable, but in other cases, it is not sufficient.\textsuperscript{50} Likewise, the frequency of occurrence of a particular phenomenon in nature does not absolutely determine whether the phenomenon is “naturally occurring.”\textsuperscript{51}

Similarly, when determining whether an application of a law of nature or abstract idea was “inventive” enough to be patent eligible, the Court appeared to look for “bells and whistles” in an invention as indications of inventiveness that transform patent ineligible subject matter into patent eligible inventions. Despite rejecting the CAFC’s “machine or transformation test,” which the Court claimed focused too rigidly on an invention’s form,\textsuperscript{52} the Court nevertheless continues to rely on the form of an invention when determining patent eligibility. As a result, the Court’s approach will likely foreclose patentability of inventions that do not have a physical or synthetic form.

The Court’s focus on the form of an invention when applying the subject matter exclusion doctrine is not surprising given the nature of the inquiries the doctrine requires the Court to make. A rigorous application of the doctrine is simply not feasible. The Court, for example, could examine more closely whether the subject matter at hand was truly a “law of nature,” an “inventive” application of a law of nature or a “naturally occurring” phenomenon. But this would embroil the courts in confounding inquiries into issues that might require

\textsuperscript{50} Compare Funk Brothers, supra note 17, at 130 (finding a human-designed mixture of bacterial species used as a fertilizer not patent eligible), with Chakrabarty, supra note 17, at 310 (finding bacteria transformed with plasmids bearing genes encoding oil-degrading enzymes patent eligible).

\textsuperscript{51} See, e.g., Myriad, supra note 44, at 2109-10. The Court found that Myriad’s claimed isolated human genes were not patent eligible, even if the genes encoded point mutations occurred with low frequency in the natural population. Id. But, even if transcription of cDNA occurred in human cells at a very low frequency by viruses that infected the cells, the Court found that cDNA was still patent eligible. See Myriad, supra note 44, n. 8 (“The possibility that an unusual and rare phenomenon might randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable.”).

\textsuperscript{52} See Prometheus, supra note 19, at 1296 (“[T]he ‘machine or transformation test’ is not a definitive test of patent eligibility.”) (citing Bilski v. Kappos, 130 S.Ct. 3218 (2010)).
technical or scientific expertise, or perhaps even philosophical or metaphysical insight. Courts are simply not equipped to make such deep inquiries.\textsuperscript{53}

The Court could also consider the policy rationale underlying the subject matter exclusion doctrine to guide its determination. According to the doctrine, laws of nature, for example, are not patentable because of the potential danger of tying up general laws and preempting the development of many useful applications of the general law.\textsuperscript{54} If the doctrine is primarily concerned with the danger of preempting technology that could be derived from subject matter that is patented, perhaps the Court could further inquire into the likelihood that new technologies would be derived from a particular subject matter. But this is an extremely speculative inquiry. Not surprisingly, the Court has refused to consider this question in depth.\textsuperscript{55}

Thus, in the end, when applying the subject matter exclusion doctrine, the Court has resorted to a fairly superficial inquiry into whether a claimed invention is a “naturally occurring phenomenon,” a “law of nature,” or an “inventive” application of natural laws. When making the determination, the Court has tended to rely on the form of the invention. Although this may be the most practicable approach, it may not always yield a satisfactory result. For example, in \textit{Prometheus}, the Court found correlations of levels of biomarkers and physiological states in a particular context to be laws of nature, even though these are arguably not general laws of nature.\textsuperscript{56} The correlations in \textit{Prometheus} are not like general laws of physics because particular

\textsuperscript{53} See, e.g., \textit{Prometheus, supra} note 19 at 1303 (“Courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature.”).

\textsuperscript{54} Prometheus has argued that the biomarker correlations in its patent claims were “narrow” laws and should not be excluded from patent eligibility because of the concerns with tying up broad, general laws of nature. \textit{Prometheus, supra} note 19, at 1303. The Court, however, refrained from analyzing in-depth whether certain laws of nature were broad or narrow. \textit{Id.} The Court also stated that tying up even narrow laws of nature could inhibit technological progress. \textit{Id.}

\textsuperscript{55} \textit{Prometheus, supra} note 19, at 1305.

\textsuperscript{56} \textit{Prometheus, supra} note 19, at 1296-98. The Court did not delve into the issue of whether the correlations in Prometheus were narrow or general laws of nature because it claimed that courts were not well-equipped to make
biomarker correlations have narrow applicability. It is difficult to see how patenting the use of particular biomarker correlations triggers the concerns that tying up general, broadly applicable laws of nature might bring.\(^{57}\)

In sum, the subject matter exclusion doctrine creates a subjective, haphazard standard of patentability, particularly for inventions that resemble laws of nature or natural phenomena. Rigorous inquiry into whether a claimed subject matter is a law of nature or naturally occurring phenomenon and inquiry into the policies underlying the doctrine are simply not practicable for courts. Because only a superficial inquiry that focuses on an invention’s form is practicable, the Court’s application of the doctrine has largely resulted in a subjective, case-by-case determination of patent eligibility.

As a result of the Court’s focus on the form of the invention, biomarker related technologies are at risk of failing the Court’s patent eligibility analysis because of the non-physical nature of these technologies. Technologies related to personalized medicine tend to appear much like patent ineligible natural laws or phenomena. Thus, while synthetic drugs and mechanical devices used to treat a patient are likely to be patent eligible because of their physical form, methods for treating a disease using information from the presence or levels of biomarkers in a patient are not likely to be patentable.

IV. Alternative Approaches to Determining Patentability

Given how the Court has applied the subject matter exclusion doctrine, how a court will rule when determining patent eligibility of biomarker related technologies is unpredictable.

\(^{57}\) Prometheus, supra note 35, at 1349 (“[T]he claims do not preempt natural processes; they utilize them in a series of specific steps.”). The Court of Appeals for the Federal Circuit had found that Prometheus’s claimed method used correlations between biomarker levels and toxicity in a narrow context and thus did not preempt “natural processes” or a “fundamental principle.” Id.
Because the Court’s application of the doctrine has focused heavily on the form of the claimed invention, inventors and patent drafters may be able to circumvent the Court’s tests by adding more “bells and whistles” to the invention or by clever claim drafting. But this is not a long-term solution to the issue of subject matter eligibility.

Other approaches to dealing with this issue are available. One approach is to abolish the subject matter exclusion doctrine and make all subject matter eligible for patent protection. The patentability of an invention can then be determined using the other criteria set out in the patent statutes, such as the novelty and non-obviousness criteria. Another similar approach is to revert to the broad subject matter eligibility standard set out in the patent statutes. The relevant statute section states that “[w]hoever 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.” According to the statute’s plain language, a new and useful process or new and useful improvements to a process are patent eligible. Therefore, new methods of cancer treatment using personalized genomics or biomarkers should be patent eligible as “new and useful” processes. Alternatively, if Congress wishes to create a separate

58 See Sanjesh P. Sharma, Patent-Eligible Subject Matter in Light of Mayo v. Prometheus, 24 INTELL. PROP. & TECH. L.J. 9 (2012). The author noted that while some commentators have taken the Court’s decision in Prometheus as a death knell for all patents relating to personalized medicine and biomarker technology, others believe that the decision would not be interpreted or applied too broadly, since all inventions embody abstract ideas or natural laws at some level. Id. The author also analyzed recent decisions after Prometheus and concluded that Prometheus could be used both to invalidate and uphold patents. Id. at 13. Therefore, the author suggested that in view of the Supreme Court’s decision, “cautious practitioners and patentees should consider saving similar types of claims in patents and patent applications from suffering Prometheus’ fate” by “skillful drafting” that ensured that “recited steps do more than just limit the claimed process to a particular technological environment” and that the steps “do not merely add broad post-solution activity that is well-known in the art.” Id.

59 See Risch, supra note 22, at 591-93 (arguing for an approach that eliminates § 101 subject matter eligibility as a criterion for patentability). The author suggests an approach which uses other sections of the patent statutes (§§ 102, 103, 112) instead of § 101 to determine patent eligibility. Id. The author argues that “a historic review of United States Supreme Court opinions provides evidence that general patentability criteria—and not subject matter were key to the Court’s primary subject matter precedents” and that “[i]n each case reviewed, the Court’s analysis concerned the underlying patentability of the particular claim at issue- problems such as obviousness [patentability requirement under § 103] or insufficient disclosure [patentability requirement under § 112]-even if its opinions nominally recited broad subject matter limitations.” Id. at 591-92.

60 Id.

policy for protecting and incentivizing the development of technologies related to personalized medicine or biotechnology, it may draft new legislation to specifically address their patent eligibility.62

V. Conclusion

As the Court in *Prometheus* highlighted, “[p]atent protection is, after all, a two-edged sword.”63 Because the patent system incentivizes innovation by granting a limited monopoly on the patented matter, the grant of a patent will likely always run the risk of preempting or delaying creation of any technology that could derive from the patented subject matter. Presumably, the subject matter exclusion doctrine steps in to prohibit the grant of a patent when patenting the subject matter will inhibit the development of a vast array of technology that could result from using the subject matter. But at what point is it likely or certain that this technology would indeed result from use of the subject matter? At what point is the danger of preempting the development of this technology so great that a patent should not be granted to the original matter it was derived from? If a patent is not granted in the first place, will this not have an effect of disincentivizing inventors from developing any technology? Ultimately, optimal patent protection involves a complicated balance of risks involved in promoting the development of technology.

Arguably, even if it may be imperfect, the patent system without the subject matter exclusion doctrine has already achieved a satisfactory and workable balance of these risks. First,

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62 See *Prometheus*, supra note 19, at 1305 (discussing future of patent policy concerning medical diagnostic technologies). In its discussion of the appropriate policy for protecting diagnostic technologies, the Court suggested that Congress may craft “more finely tailored rules” where necessary. Id. The Court hesitated from making extensive policy decisions regarding the protection of diagnostic technologies. Id.

63 Id.
the patent system grants only a limited monopoly on an invention. When the patent expires, the invention is available to everyone. Therefore, any new technology deriving from the invention likely would not be entirely foreclosed, but perhaps might simply be delayed. Also, the patent system provides limited exceptions to infringement for experimental use. Finally, it is always possible that the patent holder may grant other parties rights to develop the invention during the term of the patent. Thus, the patent system builds in features to handle the risk of preempting derivative technology, while also recognizing the importance of incentivizing the creation of new technology.

Whatever additional flexibility or benefit the subject matter exclusion doctrine adds to the patent system is outweighed by its unworkable standards and unpredictable results. The doctrine involves highly complicated and speculative inquiries, which courts are ill-equipped to handle. Further, because the doctrine provides no workable standards for the courts, courts may use the doctrine to effect policies unrelated to patent policy. For example, the results in *Prometheus* and *Myriad* were popular with many who saw the results as a step towards reducing healthcare costs and making life-saving technology available to everyone. Perhaps some may argue that the use of the subject matter exclusion doctrine to achieve popular or much-needed healthcare policy results might be desirable, at least in the short term. But in the long run, the consequences of applying the doctrine will pose a great risk of disincentivizing the creation of new technology because courts are unable to apply the doctrine in a predictable manner.

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64 See 35 U.S.C. § 154 (defining the term of a patent, which is generally 20 years from the time of the patent application is filed).
65 For details on the experimental use exception to patent infringement, see, e.g., Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. Chi. L. Rev. 1017 (1989); Ronald D. Hantman, Experimental Use as an Exception to Patent Infringement, 67 J. Pat. & Trademark Off. Soc’y 617 (1985).
particularly to technologies related to personalized medicine. The unpredictability of the application of the subject matter exclusion doctrine will ultimately weaken the incentive to develop new personalized medicine technologies because investors will be less willing to invest in developing new technology when its patentability is uncertain.\(^6\)

As it stands, the Court’s use of the subject matter exclusion doctrine threatens to exclude personalized medicine technology from patent protection. The uncertain status of their patent eligibility may ward off investment into further development of personalized medicine. With the future of cancer medicine heading towards personalized medicine technologies, an unworkable patent doctrine should not risk jeopardizing the advancement of technology that holds tremendous promise for improving disease treatment.

\(^6\) See, e.g., Brief of Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Respondent, Mayo Collaborative Servs. v. Prometheus Labs., 132 S.Ct. 1289 (2012) (No. 10-1150), 2011 WL 5373698 (“At present, tremendous and life-saving advances are being made with respect to various kinds of medical processes, including new uses for existing pharmaceuticals and processes for ‘personalized’ medicine. These advances, which entail extraordinary risk and expense on the part of the pharmaceutical and biotechnology industries, likely would not take place without the certainty and stability provided by the promise of patent protection.”); Brief of American Intellectual Property Law Association as Amicus Curiae Supporting Respondent, Mayo Collaborative Servs. v. Prometheus Labs., 132 S.Ct. 1289 (2012) (No. 10-1150) 2011 WL 5373692 (“One of the greatest challenges facing the personalized medicine industry is obtaining funding for the necessary clinical research [and] the availability of patent protection is essential to obtaining that funding. A ruling that novel and nonobvious diagnostic methods are ineligible for patent protection would cripple the nascent personalized medicine industry, to the detriment of the public.”).