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THE ABSURDITY OF PATENT INELIGIBLE CATEGORIES: THE DISCREPANCY BETWEEN THE ARIOSA AND CELLZDIRECT DECISIONS HIGHLIGHTS THE PROBLEMS CREATED BY FORMALISTIC ADJUDICATION OF PATENT ELIGIBILITY

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ABSTRACT

The Constitution granted Congress power to promote "the progress of science and the useful arts" by rewarding innovation with patent rights. Patenting innovation will inevitable conflict with protecting access to knowledge and the material sources of creativity. To balance this conflict, Congress passed 35 U.S.C. § 101 ("Section 101") to prevent patenting subject matter that could harm progress. The Supreme Court's interpretation of Section 101 has led to ill-defined patent restrictions, causing the Federal Circuit to find a novel diagnostic method patent ineligible in *Sequenom v. Ariosa*, whereas as a much simpler method of cryopreserving cells was found patent eligible in *Rapid Litig. Mgmt. v. CellzDirect.* To understand the mistakes leading to the exclusion of diagnostic patents and pave a road forward for Section 101, this Note analyzes the Supreme Court's adjudication of Section 101 through the lenses of the two major approaches to legal decision-making: formalism and realism. The Supreme Court's approach to Section 101 is formalistic because it forces the patent eligibility doctrine into simple categorical rules and it avoids engaging with the scientific and technological communities. A formalistic approach to Section 101 is bound to fail because of the conflicting policies that must be balanced to promote the progress of science and technology cannot be shoehorned into simple categories. A legal realist approach, however, would seek guidance from science philosophy to understand what science and technology is, what distinguishes these two fields, and what drives them forward. Little attention has, however, been given science philosophy in the patent eligibility debate. This Note seeks to integrate science philosophy and patent law to better understand how the patent system affects the progress of science and technology. This integration reveals that technological innovation that generates material benefits from known facts can be patented without interfering with scientific discovery of new facts and ideas. Basing patent eligibility on this distinction would include diagnostic methods as patent eligible technology.

I. INTRODUCTION

The Constitution grants 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."[1] The patent eligibility doctrine, encoded in 35 U.S.C. § 101 ("Section 101"), is meant to ensure that the patent system

[1] U.S. CONST. art. I, § 8, cl. 8.

promotes progress by balancing the inventor's property rights with protecting the public domain from being depleted by private ownership.[2] Achieving this balance remains, at most, modestly successful.[3] The Supreme Court has sought this balance by establishing a list of patent ineligible subject matter categories that are thought to harm innovation and the progress of science.[4] Most legal scholars think that this approach confuses more than it clarifies the patent eligibility doctrine.[5] This Note argues that the Supreme Court's reliance on ill-defined terminology to adjudicate patent eligibility is formalistic. Legal realism combined with a thorough understanding of the philosophy of science can pave the road for a patent eligibility doctrine that is in tune with the scientific and technological communities.

Formalism is a mode of legal reasoning and decision-making that depends on deduction from general principles.[6] This reliance on an

[2] 35 U.S.C. § 101 (2012).

[3] *See, e.g.,* John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609 (2009) (arguing that the patent eligibility doctrine consists of failed rules and some modestly successful standards).

[4] *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119–20 (2013) (holding that genomic DNA is not patent eligible subject matter because it is a naturally occurring product); Mayo Collaborative Servs. v. Prometheus Lab., Inc., 132 S. Ct. 1289, 1300–01 (2012) (arguing that inventions that claim laws of nature are patent ineligible because they cover an ever expanding range of phenomenon); Bilski v. Kappos, 130 S. Ct. 3218, 3221 (2010) ("This Court's precedents provide three specific exceptions to § 101's broad principles: 'laws of nature, physical phenomena, and abstract ideas.'" (citing Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

[5] Numerous legal scholars have pointed out the ambiguity of the reasoning behind the subject matter eligibility doctrine and called for clearer guidelines. *See* J. Jonas Anderson, *Applying Patent-Eligible Subject Matter Restrictions*, 17 VAND. J. ENT. & TECH. L. 267, 268 (2015) ("Virtually since the inception of the patent system, there have been vigorous debates about which sort of innovations should be eligible for patent protection and which should not."); Christopher Beauchamp, *Patenting Nature: A Problem of History*, 16 STAN. TECH. L. REV 257, 271 (2013) (describing the origin of the product of nature exception as "murky" and "hazy"); Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski's Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. 1289, 1290 (2011) (describing the reasoning behind the subject matter eligibility doctrine as "murky and conflicting"); Jacob S. Sherkow, *The Natural Complexity of Patent Eligibility*, 99 IOWA L. REV. 1137, 1154 (2014) ("Patent eligibility's ever growing list of excluded 'sciency things' does little, if anything, to explain what exactly natural 'laws,' 'phenomena,' or 'products' *are*.") (emphasis in original).

[6] *See* Coppage v. Kansas*,* 236 U.S. 1, 14 (1915) (holding that freedom of contract can be deduced from the constitutional right of property); CHRISTOPHER COLUMBUS LANGDELL, A SELECTION OF CASES ON THE LAW OF CONTRACTS: WITH REFERENCES AND CITATIONS v-vii (Boston, Little, Brown, & Co. 1871) (stating that

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autonomous system of rules to decide cases allows the courts to ignore the underlying conflicting policies of the law.[7] Realists oppose this conception of legal reasoning, and instead, urge a pragmatic approach to legal reasoning that is based on understanding the community's applicable law.[8] Rather than the mechanical application of rules to facts as suggested by the formalists, the realists propose that the "judges should apply rules in light of their purposes, looking to the goals of the rules and their social effect."[9]

The goal of Part II of this Note is to analyze the patent eligibility doctrine by using formalism and realism as a dialectic framework. This analysis will demonstrate that the Supreme Court's approach to determine patent eligibility is formalistic because it depends on using categories that lack clear definitions. This indeterminacy allows the courts to avoid making a reasoned choice between the conflicting policies of the patent eligibility doctrine, resulting in decisions that do not serve the purpose of this doctrine.[10] Next, this section shows that legal realism can provide an analytical framework for adjudicating patent eligibility that does not ignore the conflict between the individual inventor and the public. Furthermore, this realist approach must be based on a thorough understanding of what science is, how science progresses, and the clear distinction between science and technology.[11] Science philosophers have established that technology

law is a science where general principles are induced from cases, and particular rules are deduced from these principles); Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193, 193 (1890) (explaining that policy considerations were used only to generate first principles and that particular rules were deduced from these principles to adjudicate cases).

[7] *See* Duncan Kennedy, *Legal Formality*, 2 J. LEGAL STUD. 351, 358 (1973) (stating that "[f]ormality consists in the attempt to accomplish substantively rational results—i.e., to achieve outcomes that 'maximize' a set of conflicting purposes—through the substantively rational formulation and mechanical application of rules").

[8] *See, e.g.,* OLIVER WENDELL HOLMES, *THE COMMON LAW (1881), reprinted in* AMERICAN LEGAL REALISM 9 (William W. Fisher III, Morton J. Horwitz & Thomas A. Reed eds., 1993) (arguing that cases cannot be decided by logic alone); Felix Cohen, *Transcendental Nonsense and the Functional Approach*, 35 COLUM. L. REV. 809, 821 (1935) (arguing that the legal concepts used by the formalists are meaningless if they are not defined by the way these terms are used in the real world); Roscoe Pound, *The Call for a Realist Jurisprudence*, 44 HARV. L. REV. 697, 702–03 (1931) (arguing that formalistic adjudication ignores value judgment).

[9] Joseph William Singer, *Legal Realism Now*, 76 CAL. L. REV. 465, 501 (1988).

[10] *See generally* Grant Lamond, *Precedent and Analogy in Legal Reasoning*, THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (June 20, 2006), http://plato.stanford.edu/entries/legal-reas-prec/.

[11] *See* MICHAEL POLANYI, PERSONAL KNOWLEDGE, 130 (Univ. of Chi. Press 1958).

is the use of known facts to generate inventions that have material and economic advantages, whereas science progresses by applying tacit knowledge to discover new ideas and facts.[12] Thus, this Note suggests that these technological inventions are patent-eligible subject matter even if they are not physical products or artifacts. The requirements that technological inventions must be based on known facts and give material and economic advantages ensure that patenting these inventions will not impede scientific progress.[13] Scientific discoveries and general strategies of problem solving should, however, be restricted subject matter because their exclusion will deplete the sources of scientific progress.[14]

In Part III of this Note, the realist approach established in Part II is used to analyze the Supreme Court's decisions that established the "laws of nature" and "naturally occurring products" patent ineligible categories. These categories are not sufficiently defined to serve as a basis for a reasoned choice between the conflicting policies underlying the patent eligibility doctrine.[15] The realist approach requires that categories of "laws of nature" and "naturally occurring products" must be abandoned because they allow the courts to avoid making a reasoned choice based on the purpose of the patent eligibility doctrine.[16] This part will demonstrate that basing patent eligibility on a clear definition of technology will reward innovation while protecting the progress of science.

Finally, Part IV will discuss the consequences the current patent eligibility doctrine has for the biotechnology industry and, in particular, for diagnostic methods that depend on using genetic information and DNA sequences. The Supreme Court's decisions have excluded medical diagnostic methods from patentability.[17] Diagnostic methods involve using known facts and the relationship

[12] *Id.* at 185–90.

[13] *See id.* at 187.

[14] *See id.*

[15] Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1380 (Fed. Cir. 2015) (Linn, J., concurring) (stating that Mayo Collaborative Serv. v. Prometheus Lab., Inc., "represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain[.]" 132 S. Ct. 1289 (2012)).

[16] *See* POLANYI, *supra* note 11, at 178.

[17] *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1301 (2012) (reasoning inventions that claim laws of nature are patent ineligible because they cover an ever-expanding range of phenomenon). *See also Ariosa Diagnostics, Inc.,* 788 F.3d at 1380 (Linn J., concurring) (stating that in comparison to Mayo, Ariosa "represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain").

between them for material benefits; whereas, science progresses by solving problems that were unsolvable until the discovery of new facts or new relationships.[18] The diagnostic method at issue in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*[19] only claimed a method to use the known fact that pregnant mothers with pre-eclampsia have cffDNA in the blood to diagnose pre-eclampsia.[20] Excluding this method will not prevent scientists from discovering currently unknown ways to diagnose pre-eclampsia or other uses for cffDNA.[21] On the other hand, the Federal Circuit found a method of cryopreserving cells patent eligible in *Rapid Litigation Management, Ltd. v. CellzDirect, Inc.*[22] without satisfactorily explaining how this method avoided Section 101 exclusion and *Ariosa* did not.[23] Basing patent eligibility on an accurate distinction between science and technology would, therefore, ensure that technological innovation is awarded patent rights while protecting access to the methods and tools that drive scientific progress.

II. APPROACHES TO ADJUDICATION OF THE PATENT ELIGIBILITY DOCTRINE

A. The Purpose of the Patent Eligibility Doctrine

Section 101 states that patent rights can be granted to "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[24] These categories of patent eligible subject matter were meant to cover unforeseeable future developments, to ensure that patents are granted to inventions that fit within general industry borders, and to avoid interference with scientific progress.[25]

Worried that this liberal interpretation of Section 101 would result in patenting subject matter that is harmful to innovation and science, the Supreme Court established that "laws of nature," "natural phenomena," "abstract ideas," and "products of nature" are exempt

[18] *See* discussion *supra* Section III.B.

[19] *Ariosa Diagnostics, Inc.*, 788 F.3d at 1373.

[20] *Id.*

[21] *Id.* at 1377–78.

[22] Rapid Litig. Mgmt., Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1045 (Fed. Cir. 2016).

[23] *Ariosa Diagnostics, Inc.*, 788 F.3d at 1374, 1376.

[24] 35 U.S.C. § 101 (2012).

[25] *See, e.g.,* Application of Bergy, 596 F.2d 952, 974–79 (C.C.P.A. 1979) (arguing that the purpose of Section 101 of the patent act was to draw general industry border and not provide a list of distinct patent eligible subject matter categories).

from patenting to protect the basic tools and sources for scientific progress.[26] Many scholars have criticized these patent exemptions for unfairly biasing the biotechnology industry and for not being defined clearly enough to promote the purpose of the patent eligibility doctrine.[27] But it has also been argued that these exemptions are important as backup mechanisms to invalidate patents that have met the other patent requirements, but would nevertheless cover subject matter that would stifle the progression of science.[28]

A study by Jonas Anderson organized the various roles Section 101 can have in promoting scientific and technological progress into four categories: pre-emption, innovation-harm, over-reward, and non-economic.[29] Anderson further found that Section 101 would be best suited to prevent innovation-harm and promote non-economic goals since these functions can best be fulfilled with the categorical approach of Section 101.[30] Preventing pre-emption would require the patent office to determine the full scope of the patent, which may not be practically possible.[31] Similarly, determining whether an innovation would have been made without the reward of a patent would also have to be determined on a case-by-case basis, and it would be difficult to establish categories of ineligible subject matter to prevent this over-reward effect.[32] Thus, the categorical approach of Section 101 would be best suited to exclude patents that harm innovation and patents that are immoral.

Identifying rules that exclude subject matter that is harmful for innovation and promote the purpose of the patent system has proven to be difficult. The legal scholar John Duffy suggested that these rules must be identified by a process of trial and failure.[33] For example,

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[26] *See, e.g.,* Bilski v. Kappos*,* 130 S. Ct. 3118, 3221, 3225 (2010).

[27] *See* sources cited *supra* note 5.

[28] *See* Rebecca S. Eisenberg, *Wisdom of the Ages or Deadhand Control? Patentable Subject Matter for Diagnostic Methods after In re Bilski*, 3 CASE W. RES. J.L. TECH. & THE INTERNET, 1, 54–56 (2012) (arguing that Section 102 (novelty) is not a basis for rejecting natural products or phenomena because this provision precludes patenting of an invention that was identified in prior sources of human knowledge). Furthermore, in some cases the difficulty of applying the particular requirements of written description fails to limit the scope of patents, and the patent eligibility doctrine could in these cases be used to reign in the patent so that it does not impede the progress of science. *See id.*

[29] J. Jonas Anderson, *Applying Patent-Eligible Subject Matter Restrictions*, 17 VAND. J. ENT. & TECH. L. 267, 286–92 (2015).

[30] *Id.* at 287.

[31] *Id.* at 287–90, 292.

[32] *Id.* at 287–88, 292.

[33] Duffy*, supra* note 3, at 623–38.

before the *Diamond v. Chakrabarty*[34] decision, life was clearly unpatentable; but when technological developments made it possible to change the properties of living organisms, patent eligibility had to be extended to life.[35] In addition, the rules against patentability of "changes in form and proportions," "new uses," and "methods of medical treatment" have all been discarded and replaced with new rules.[36] However, since the rules against "laws of nature," "naturally occurring products," and "physical phenomenon" have been left undefined,[37] it is not clear how these rules can be tested. Thus, a categorical approach to Section 101 determination of categorical subject matter has been largely unsuccessful.

B. The Supreme Court's Approach to Patent Eligibility is Formalistic

The problem with the current Section 101 jurisprudence seems to be that it relies on legal formalism in its attempt to shoehorn the complex relationship between rewarding innovations with patent grants and protecting the sources of creativity into distinct categories. Legal formalism sees the practice of law as a science where judges decide cases by applying general rules "with constant facility and certainty to the ever tangled skein of human affairs."[38] According to legal formalism, the law consists of a few first principles from which particular rules that are applicable to specific fact patterns can be logically deduced.[39] The purpose and goals of these first principles are thought to be preserved when applied by logical deduction to particular cases.[40] Thus, the formalist system avoids having to deal directly with the underlying conflicts of the law, and judges merely have to define the boundaries of the categories that the facts of the

[34] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[35] *See id.* at 309–10 (holding that a bacteria strain with new properties is patent eligible composition of matter because this bacterium is not found in nature).

[36] Duffy, *supra* note 3, at 624–38.

[37] *See* sources cited *supra* note 5.

[38] CHRISTOPHER COLUMBUS LANGDELL, *A SELECTION OF CASES ON THE LAW OF CONTRACTS*, *reprinted in* READINGS IN THE PHILOSOPHY OF LAW 125 (John Arthur & William H. Shaw eds., Prentice Hall 2001).

[39] *See* AMERICAN LEGAL REALISM, SUPRA NOTE 8, at xii (stating that by 1900, the law was considered "like geometry," where "[e]ach doctrinal field revolved around a few fundamental axioms, derived primarily from empirical observation of how court had in the past responded to particular sorts of problems").

[40] *See* Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193, 193–97 (1890) (explaining that policy considerations were used only to generate first principles that particular rules were deduced from these principles to adjudicate cases).

cases are sorted into.[41]

Legal formalism provides predictability of adjudication and ensures the autonomy of the legal system.[42] For example, rather than discussing policy issues concerning the validity of laws passed by governments hostile to the United States during the Reconstruction Era after the Civil War, the *Texas v. White*[43] Court formalistically decided the case under the Constitution alone and ignored intricate issues concerning Reconstruction laws.[44] Thus, the legal formalist approach allowed the Court to assert its authority and the strength of the Union at a time when authority and conservation were necessary for the nation to prevail.[45]

Legal formalism focuses on the law solely as a logical system and ignores the law's connection to "human needs" and "felt necessities."[46] Although it is logical, as the Court in *Plessy v. Ferguson*[47] stated, that a law separating two races does not necessarily make one of the races inferior to the other, the effect is clearly that this ruling promoted the segregation policy that continued the subordination of African-Americans.[48] This abstract treatment of the stigmatizing effects of segregation in *Plessy* illustrated that unrestricted legal formalism reduces the law to a valueless logical game.

The legal formalist approach was also inept to deal with dramatic societal changes. For example, the courts failed to realize the new social reality that emerged during the Progressive Era and continued to formalistically adjudicate conflicts, resulting in socially undesirable results.[49] This formalism reached its high point in *Lochner v. New York*[50] and *Coppage v. Kansas*,[51] in which the Supreme Court decided that the freedom of contract between employer and employee must be protected from government interference. For the formalist courts, like *Lochner* and *Coppage*, "the key legal question, in every instance of dispute, was whether the relevant actors stayed within their own

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[41] *Id.*

[42] *See* Texas v. White, 74 U.S. 700 (1868).

[43] *Id.* at 705.

[44] *Id.* at 700, 732.

[45] *Id.* at 725–37.

[46] Stephen A. Siegel, *John Chipman Gray and the Moral Basis of Classical Legal Thought*, 86 IOWA L. REV. 1513, 1524 (2001).

[47] Plessy v. Ferguson, 163 U.S. 537, 551 (1896).

[48] Brown v. Bd. of Educ., 347 U.S. 483, 495 (1954).

[49] *See* KERMIT L. HALL & PETER KARSTEN, THE MAGIC MIRROR: LAW IN AMERICAN HISTORY 208–30 (2d ed. 2009).

[50] *See, e.g.*, Lochner v. New York, 198 U.S. 45, 64–65 (1905).

[51] *See, e.g.*, Coppage v. Kansas, 236 U.S. 1, 26 (1915).

protected sphere of activity or had crossed over the boundary and invaded the sphere of another."[52] According to this theory, formalistic adjudication is merely a process of defining the boundaries between the public and private sphere.[53]

The increasingly intolerable approach of the formalistic courts during the Progressive Era resulted in the anti-formalist legal realism movement.[54] The legal realists synthesized the problems of formalism into three principles. First, legal realism warned against mechanistic application of general rules to particular cases, because legal terms are indeterminate and need to acquire meaning from sources outside the law.[55] Second, legal realism warned against relying on precedential decisions that are no longer relevant because of societal and technological changes.[56] Third, legal realism demanded that judges must decide between inevitably conflicting policies, whereas formalistic reasoning allows judges to avoid making this choice of values.[57] Given this, the courts should not apply a formalistic

[52] Elizabeth Mensch, *The History of Mainstream Legal Thought*, in THE POLITICS OF LAW 23, 28–32 (David Kairys ed., 3d ed. 1998).

[53] Morton J. Horwitz, *The History of the Public/Private Distinction*, 130 U. PA. L. REV. 1423, 1426 (1982).

[54] *Id.* at 1426–27.

[55] *See* Felix Cohen, *Transcendental Nonsense and the Functional Approach*, 35 COLUM. L. REV. 809, 821–23 (1935) (proposing the "functional approach" that requires that legal concepts are defined in a way they are actually used in contrast to mechanically applying legal concepts); OLIVER WENDELL HOLMES, *THE COMMON LAW (1881), reprinted in* AMERICAN LEGAL REALISM, *supra* note 8, at 9 ("The life of the law has not been logic: it has been experience."); Roscoe Pound, *The Call for a Realist Jurisprudence*, 44 HARV. L. REV. 697, 702–03 (1931) (arguing that a law analogous to mathematics is not possible because mathematical exactness can only be achieved by excluding the theories of values underlying every decision).

[56] *See* Oliver Wendell Holmes, *The Path of the Law*, *reprinted in* AMERICAN LEGAL REALISM, *supra* note 8, at 15, 20 (stating that tort law is based on "the old days of isolated, ungeneralized wrongs, assaults, slanders, and the like"; whereas now it is systematic incidents of well-known businesses like the railroad industry and factories); Roscoe Pound, *Liberty of Contract*, 18 YALE L. J. 454, 454 (1909) (asking: "Why do we find a great and learned court in 1908 taking the long step into the past of dealing with the relation between employer and employee in railway transportation, as if the parties were individuals—as if they were farmers haggling over the sale of a horse?"); JOHN CHIPMAN GRAY, *THE NATURE AND SOURCES OF THE LAW (1897)*, *reprinted in* AMERICAN LEGAL REALISM, *supra* note 8, at 34, 35 (stating that "precedents are not absolutely binding, they can be disregarded when flatly absurd or unjust").

[57] *See* Lochner v. New York, 198 U.S. 45, 53–56 (arguing that "[t]he right to purchase or to sell labor is part of the liberty protected by this amendment," so "[o]f course the liberty of contract relating to labor includes both parties to it;" the majority in this case, therefore, refused to acknowledge the conflicts that arise when both parties have the same privilege of right to contract); Oliver Wendell Holmes,

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approach of adjudication when the terms of the applicable law are indeterminate, the case involves issues that have undergone dramatic changes, and the applicable law has underlying conflicting policies that must be dealt with.

Applying this legal realist critique to the patent eligibility doctrine reveals the problems of the current formalistic Section 101 jurisprudence. First, the Supreme Court has not defined the "laws of nature" and "abstract ideas" categories, creating indeterminate patent eligibility rules.[58] Second, applying patent subject matter restrictions of "products of nature" decided in 1911 to modern day biotechnology inventions is like analogizing 18th century isolated wrongs with 20th century railroad accidents.[59] This criticism is particularly important for adjudication of patent eligibility where the rules must be applied to rapidly changing technological and scientific developments. Third, by using rules against "laws of nature" and "products of nature," the courts can easily adjudicate patent eligibility cases without having to engage the scientific communities and make a reasoned choice between conflicting policies.[60] The indeterminacy of the terms used in the patent eligibility rules allows the courts to avoid rigorous analysis of the cases and to avoid taking responsibility for their decisions.[61] Given this, a legal realist approach to adjudicate patent eligibility under Section 101 might be better.

C. The Legal Realist Approach to Adjudication: Generating New Visions of Law

Legal realism arose as a critique of the failure of the courts to acknowledge that the public/private and individualist/paternalist distinctions were gone, and new visions for the role of judges beyond that of boundary-definers were needed.[62] The Supreme Court's approach to Section 101 is currently stuck trying to define the boundaries between patent eligible and ineligible subject matter categories.[63] Replacing this formalistic mode of adjudication for a

The Path of the Law, *reprinted* in AMERICAN LEGAL REALISM, *supra* note 8, at 15, 19 (arguing that there is judgment behind the logical deduction: "You can give any conclusion a logic form").

[58] *See supra* note 5 and accompanying text.

[59] Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (C.C.S.D.N.Y. 1911), *aff'd in part*, *rev'd in part sub nom.* Parke-Davis & Co. v. H K Mulford & Co., 196 F. 496 (2d Cir. 1912); *see also infra* Section II.B.

[60] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 134–35 (1948).

[61] *Id*.

[62] *See supra* note 55 and accompanying text.

[63] *See generally* Mayo Collaborative Servs. v. Prometheus Labs., Inc. 132 S. Ct.

continued . . .

legal realist approach is, therefore, necessary to generate a new vision for how Section 101 can promote the progress of science.

The legal realist approach to adjudication demands that legal concepts get their meaning from experience.[64] Furthermore, social policy should be considered the "gravitational field" that gives weight to the rules.[65] The rules do not have value in themselves, and there is no such thing as objectivity because the judges will always be guided by their values and political inclinations.[66] The legal realist approach, therefore, allows creative legal thought by asserting that no rules are objective heavenly objects, but rather they are creations of the human mind.[67] The legal rules are of course important, and many cases can easily be adjudicated by applying rules to fact patterns.[68] But under circumstances where a rule consistently generates undesirable outcomes or the decisions are unpredictable because the terms of the rule are indeterminate, the judge should be required to eradicate the dysfunctional rule and generate a new vision for the law.

The failure of formalism to generate new visions of the law when necessary was exposed by the Great Depression in the 1930s.[69] According to legal scholar G. Edward White, the Court's decisions that crippled New Deal legislation in the wake of the Depression triggered a public outrage against the Court, leading to a fundamental change in adjudication where the Constitution was viewed as adaptable to changing circumstances and not as a list of unchanging general principles.[70] Consistent with the idea of an adaptable Constitution, the *Nebbia v. New York*[71] Court eviscerated the bright line distinctions between public and private spheres in holding that the state could regulate the milk industry because "equally fundamental [as] private right is that of the public to regulate it in the common interest."[72] The *Nebbia* Court decided the case based not on the law in isolation, but considering the social consequences of the decision.[73] This legal realist approach allowed the Court to generate law with new vision by understanding the social activity related to the dispute and

1289 (2012).

[64] Cohen, *supra* note 8, at 821–34.

[65] *Id.* at 834.

[66] *Id.* at 833.

[67] *Id.*

[68] *See generally id.*

[69] G. Edward White, *The "Constitutional Revolution" as a Crisis in Adaptivity*, 48 HASTINGS L.J. 867, 868–74 (1997).

[70] *Id.*

[71] Nebbia v. New York, 291 U.S. 502, 522–27 (1934).

[72] *Id.* at 523.

[73] *Id.* at 538–39.

by abolishing the formalist federal-state distinctions.[74] Thus, legal realism allowed the New Deal Court to adapt the Constitution to meet the challenges of a national crisis, which the former Court had failed to do.

A legal realist approach to adjudication allows judges to generate new visions for the law not only when facing a national crisis, but also when facing more individualized concerns. For example, Holmes created a new vision for freedom of speech by asserting that the First Amendment protects "free trade in ideas," so that the best ideas will be selected in the market place.[75] Furthermore, the *Brown v. Board of Education*[76] Court created a new world where African-Americans had substantially increased opportunities for equal education.[77] In the more recent *Obergefell v. Hodges*[78] case, the Court created a world where "couples of the same-sex may not be deprived of that right [to marry] and that liberty [to marry]" by applying a distinctly realist approach to adjudication.[79] The *Obergefell* Court outlined the history of marriage and found that "the marriage laws enforced by the respondents are in essence unequal: same-sex couples are denied all the benefits afforded to opposite-sex couples and are barred from exercising a fundamental right."[80] This inequality was revealed by changes in society over the last century: both in the increasing list of government benefits afforded married couples and in realizing the harm this inequality caused same-sex couples.[81] Thus, rather than formalistically deciding the case based on the idea that marriage was historically understood to be between man and woman, the Court expanded the right to marry to same-sex couples and created a world where same-sex couples were free from the stigmatizing effects of being excluded from a fundamental constitutional, as well as human right, to marry.[82] In conclusion, if formalistic adjudication was allowed to dominate without a legal realist counterpoint, we would live in a world without labor protections, free trade of ideas, integrated schools, and equal marriage rights for same-sex couples.

The legal failure of formalism is a failure to engage sufficiently with the case to ensure that the decision promotes justice and panders

[74] *Id.*

[75] Abrams v. United States, 250 U.S. 616, 630 (1919).

[76] Brown v. Bd. of Educ., 347 U.S. 483, 494–95 (1954).

[77] *Id.* (rejecting "[A]ny language in Plessy v. Ferguson contrary to this finding" that segregation has a "detrimental effect upon the colored children").

[78] Obergefell v. Hodges, 135 S. Ct. 2584, 2604–05 (2015).

[79] *Id.*

[80] *Id.* at 2604.

[81] *Id.* at 2601.

[82] *Id.* at 2602.

to neither the rich and powerful nor to political interests. Legal realism can, however, commit the same failure.[83] For example, in *Korematsu v. United States*,[84] the Court upheld as constitutional an Executive Order that allowed the army to curfew U.S. citizens of Japanese ancestry.[85] The Court denied that race had anything to do with the selection of citizens with Japanese ancestry, but rather the curfew was instituted out of military necessity.[86] A formalist approach that ignored the politics and applied "strict scrutiny" to this case would clearly have found this Executive Order unconstitutional. Left unchecked, both formalist and realist approaches to adjudication can fail. As such, both approaches are necessary to face the challenges of the modern world. Similarly, Tamanaha's historical study found no clear distinction between formalist and realist periods, and that understanding judging requires a more balanced view on formalism and realism.[87] In a balanced approach to adjudication, formalism will promote predictability and autonomy of the courts; whereas realism can envision a new law when the old law produces undesirable results.[88] Thus, formalism and realism can balance and restrict each other to guide the development of the law towards its ultimate purpose.

The ultimate purpose of Section 101 is to promote the "Progress of Science and useful Arts."[89] A formalist approach to seek this purpose is doomed to fail because of the dynamic nature of scientific and technological progress and the complexity of the forces that drive that progress. In contrast, a legal realist approach would seek guidance from science philosophy to generate a new vision for the patent system that can reward innovation with exclusive patent rights while protecting the public sources of creativity. Science philosophy has developed a thorough understanding of what science and technology is and how these human endeavors progress.[90] Thus, integrating scientific and legal thought could help develop a patent eligibility doctrine that gets it weight from the gravitational pull of promoting science.

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[83] *See, e.g.*, Korematsu v. United States, 323 U.S. 214 (1944).

[84] *Id.* at 215.

[85] *Id.* at 223.

[86] *Id.*

[87] Brian Z. Tamanaha, *Balanced Realism on Judging*, 44 VAL. U.L. REV. 1243, 1245 (2010).

[88] *Id.* at 1258–60.

[89] U.S. CONST. art. I, § 8, cl. 8.

[90] *See generally* THOMAS S. KUHN, *THE STRUCTURE OF SCIENTIFIC REVOLUTIONS,* 144–59 (Univ. of Chi. Press, 1996) (comparing verification, falsification, and paradigm shift approaches to understanding science).

D. Integrating Scientific and Legal Thought: Basing the Patent Eligibility Doctrine on Distinguishing Science and Technology.

Since the main purpose of the patent eligibility doctrine is to ensure that the patent system advances scientific and technological progress, determining patent eligibility must be based on a clear understanding of what science is and how it progresses. There are two major schools of thought about what science is and how science progresses: (i) Popper's logical positivism,[91] and (ii) Kuhn's normal science.[92] According to logical positivism, science is uniquely characterized by purging its theories through a process of making risky predictions designed to falsify the theories.[93] For example, Einstein's theory of relativity predicted that light must bend in gravitational fields, resulting in the theory that light coming from a distant star would be deflected by the Sun without any empirical observation of this actually happening.[94] This light-bending effect was first shown years later by Eddington, dramatically proving Einstein's theory.[95] This capacity of the natural sciences to make accurate predictions that can be falsified seems to distinguish science from any other explanatory system.

The problem with Popper's account of the scientific method is that it relies on dramatic and rare events like Einstein's discovery of relativity rather than the more common incremental scientific discoveries.[96] By studying these more common scientific events, the science philosopher Kuhn showed that scientists spent most of their time trying to solve problems posed by the scientific field they were working in rather than falsifying hypotheses like Popper had proposed.[97] Furthermore, the scientists, according to Kuhn, were for the most part not even aware of the scientific paradigm they worked within.[98] The failure of a prediction would, therefore, only result in refuting the scientist's own hypothesis and not the overall corpus of

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[91] *See* Karl Popper, *Science: Conjectures and Refutations, in* PHILOSOPHY OF SCIENCE: THE CENTRAL ISSUES 3, 7 (Martin Curd et al. eds., 2013) (asserting that "the criterion of the scientific status of a theory is its falsifiability, or refutability, or testability").

[92] *See* KUHN, *supra* note 90*, at* 35 (stating that "[p]erhaps the most striking feature of the normal research problems we have just encountered is how little they aim to produce major novelties, conceptual or phenomenal").

[93] *See* Popper, *supra* note 91, at 7.

[94] *Id.* at 6–7.

[95] *Id.* at 4.

[96] *Id.*

[97] *See* KUHN, *supra* note 90, at 5–6.

[98] *Id.*

science.[99] According to Kuhn, science progresses by assuming the correctness of scientific theories and solving problems by applying scientific theories to explain events in the world.[100]

Neither Popper nor Kuhn distinguishes science from technology in their attempts to identify the forces that drive these endeavors forward.[101] Popper focused on the more basic science that seeks to explain how the universe works; whereas, Kuhn focused on technology development.[102] However, the forces that drive scientific and technological progress are vastly different.[103] The science philosopher Polanyi found that "in science originality lies in the power of seeing more deeply than others into the nature of things, while in technology it consists in the ingenuity of the artificer in turning known facts to a surprising advantage."[104] According to Polanyi, science progresses by the intellectual passion of scientists for discovering new knowledge, and forcing science into a utilitarian scheme will cause "the love of pure science [to] falter and die."[105] Thus, science generates new facts and ideas without a concern for economic utility, whereas technological inventions must gain economic and material advantages.

Science and technology also differ by the way they progress. The scientific process of discovery is not a "strictly logical performance," but requires what Polanyi calls tacit knowledge.[106] A scientist is guided through the process of discovering solutions to scientific problems by his tacit knowledge gained by experience and deep engagement with his subject of investigation.[107] Tacit knowledge also underlies the creative process of artists and craftsmen, which is elegantly illustrated by the philosopher Martin Heidegger's description of how a cabinetmaker learns his art:

> His learning is not mere practice, to gain facility in the use of tools. Nor does he merely gather knowledge about the customary forms of the things he is to build. If he is to become a true cabinetmaker, he makes himself answer and respond above all to the different kinds of wood and to the shapes slumbering within the

[99] *Id.*
[100] *Id.* at 6.
[101] *See id.* at 15–16; Popper, *supra* note 91.
[102] *See* KUHN, *supra* note 92; Popper, *supra* note 91.
[103] POLANYI, *supra* note 11, at 188–92.
[104] *Id.* at 188.
[105] *Id.* at 182.
[106] *Id.* at 120–23.
[107] *Id.*

> wood—to wood as it enters into man's dwelling with all the hidden riches of its nature. In fact, this relatedness to wood is what maintains the whole craft. Without the relatedness, the craft will never be anything but empty busywork, any occupation with it will be determined exclusively by business concerns. Every handicraft, all human dealings are constantly in that danger. The writing of poetry is no more exempt from it than is thinking.[108]

The learning of the cabinetmaker is tacit knowledge, gained through experience and relatedness to the new ideas and facts waiting to be uncovered.[109] Similarly, scientists discover new ideas and facts by using their tacit knowledge and deep engagement with their object of investigation.[110] These new facts and ideas can then be applied to solve problems and develop new technologies that provide surprising advantages and give material benefits.[111]

These distinctions between science and technology are sometimes blurred by their intertwining relationship. The historical study by James E. McClellan and Harold Dorn makes clear that new technology leads to new scientific discoveries, and new scientific discoveries leads to new technology.[112] However, the requirement that technology provides an economic and material advantage will exclude science-based technologies, such as microscopes, from being considered a technology in this context. Research tools have a primarily scientific advantage and are not economical to the same extent as a cell phone.[113] This exclusion of research tools from the technological realm is also consistent with the utility requirement of the patent eligibility doctrine, which demands an invention must be operable and have some immediate utility.[114] Thus, the economic advantage and the utility requirement can be used to distinguish technology from science.

To promote the progress of scientific discovery and technological

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[108] MARTIN HEIDEGGER, *WHAT IS CALLED THINKING?* 14–15 (Harper Perennial, reprt. 2004).

[109] *Id.*

[110] *See* POLANYI, *supra* note 11, at 130.

[111] *Id.*

[112] *See* JAMES E. MCLELLAN III & HAROLD DORN, SCIENCE AND TECHNOLOGY IN WORLD HISTORY: AN INTRODUCTION 426 (Johns Hopkins Univ. Press 2006).

[113] *See id.* at 411–13.

[114] *See* Brenner v. Manson, 383 U.S. 519, 535 (1966) (holding that a particular use of the invention must be stated so that the public can benefit from it); *see also In re* Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (rejecting patent claims for EST tags because they are not immediately useful, but mere research tools).

advancement, science and technology must be clearly distinguished. Science could "falter and die" due to the brute reality of economical concerns that demand scientists to focus on utility.[115] Distinguishing science and technology would allow scientists to focus on discovery of new ideas and facts without utilitarian concerns and allow technology to gain economical benefits from generating "surprising advantages" from known facts.[116] An optimally functioning patent system can then promote science by excluding subject matter that is of mere business concern from the realm of science while providing the technological sphere optimal opportunities to gain economic advantages.

In the next section, this Note will test the findings herein on the cases that established the current patent eligibility rules that exclude laws of nature and naturally occurring products from patentability. First, these cases will be analyzed through the lens of formalism and realism. Second, the cases will be analyzed to determine whether the patents at issue claim scientific discoveries of new ideas and facts or technological inventions that are generated from known facts and that give material advantages. This analysis will reveal that restricting patent eligibility to technology will allow patenting of diagnostic methods while adequately protecting the sources of scientific progress.

III. APPLYING LEGAL REALISM AND SCIENCE PHILOSOPHY TO THE PATENT ELIGIBILITY DOCTRINE

A. Laws of Nature

The Supreme Court in *O'Reilly v. Morse* argued that allowing patent claims to laws of nature would award patent rights to unforeseeable future discoveries.[117] The Court determined that "the use of the motive power of the electric or galvanic current" would grant the inventor the exclusive right to "the discovery of a principle in natural philosophy or physical science."[118] In contrast, the dissent in Morse argued that "the application of a principle is the most important part of the invention," and without this principle, "the inventor could be protected in nothing but his first rough types."[119] The dissent in Morse went on to state:

> He who first discovers that an element or law of nature can be made operative for the production of some

[115] POLANYI, *supra* note 11, at 182.
[116] *Id.*
[117] O'Reilly v. Morse, 56 U.S. 62, 113–14 (1853).
[118] *Id* at 112, 116.
[119] *Id.* at 130, 132 (Grier J., dissenting).

> valuable result, some new art, or the improvement of some known art; who had devised the machinery or process to make it operative, and introduced it in a practical form to the knowledge of mankind, is a discoverer and inventor of the highest class. [120]

The conflict is, therefore, that patenting a law of nature will cover unforeseeable future discoveries, whereas if the principle of the invention is subtracted then the inventor may not get credit for his full invention.[121] In *Morse*, however, the Court found the claim invalid because it "c[ould] derive no aid from the specification filed."[122] Thus, the *Morse* Court determined validity of the claim by asking whether it had support in the specification and not by testing the claim against some arbitrary categories.

Rather than analyzing whether the inventor claimed beyond the patent specification, the Court in *Mayo Collaborative Services v. Prometheus*[123] determined that methods that amount to nothing more than applying a law of nature is patent ineligible under Section 101.[124] In *Mayo*, the inventor claimed a method to predict efficacy and toxicity of drug dosages based on measuring metabolic conversions of the drug.[125] The court found this correlation patent ineligible because it amounted to merely the application of a law of nature.[126] The *Mayo* Court used a two-step test to determine whether a claimed invention was merely the application of a law of nature. First, it identified the natural relations described by the patent claims; and second, it determined if the patent claims "add[ed] enough to their statements of the correlations to allow the processes they describe[d] to qualify as patent-eligible processes that apply natural laws."[127]

The Court used a formalistic approach to define what "add[ing] enough . . . to qualify as patent-eligible processes" meant by using legal sources.[128] The Court compared the claimed invention to two prior decisions: *Diamond v. Diehr*[129] and *Parker v. Flook*.[130] According to the *Mayo* Court, the *Diehr* Court found that "the overall

[120] *Id.* at 132.
[121] *Id*. at 132–33.
[122] *See id.* at 119–20.
[123] Mayo Collaborative Servs. v. Prometheus Labs., 132 S. Ct. 1289 (2012).
[124] *Id*. at 1293, 1297.
[125] *Id.* at 1296.
[126] *Id.* at 1302.
[127] *Id.* at 1297.
[128] *Id.* at 1297–98.
[129] Diamond v. Diehr, 101 S. Ct. 1048 (1981).
[130] Parker v. Flook, 437 U.S. 584 (1978).

process was patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole."[131] The *Mayo* Court argued, however, that the claimed invention in *Flook* was not patent-eligible because the process does "nothing other than providing an unpatentable formula for computing an updated alarm limit."[132] The *Mayo* Court concluded that the patentability of the claimed invention at issue was weaker than it was in *Diehr* and not stronger than it was in *Flook,* so the claimed invention was held patent ineligible under Section 101.[133] Therefore, the *Mayo* Court bases its decision on finding that in *Diehr*, the mathematical formula was integrated in the process as a whole, while the Court found no such integration in *Flook*.[134] The requirements for this integration of abstract principle with physical process were not discussed, so the distinction between *Diehr* and *Flook* remains a mystery. As discussed in part I of this Note, basing a decision on making this type of arbitrary distinction is a hallmark of failed formalistic legal reasoning.

The approach of the *Mayo* Court is formalistic because it mechanically applies the rule against a law of nature by merely saying that the invention is a law of nature.[135] Furthermore, the Court is formalistic because it relied on irrelevant precedent when it applied the *Diehr* case, involving the tire industry, and the *Flook* case, involving hydrocarbon conversion, to *Mayo*, which involved a clinical diagnostic method.[136] Finally, the Court used mechanical application of rules to avoid making a choice between the conflicting policies of patent law.[137] There is no discussion in the case about how the patent claim at issue would impede further scientific or technological development in the relevant fields. Therefore, the *Mayo* Court's process of adjudication was formalistic because it tautologically called the

[131] *Mayo*, 132 S. Ct. at 1298.

[132] *Id.* at 1299.

[133] *Id.*

[134] *See supra* text accompanying notes 131–32; *see also id.* (noting that "unlike the process in Diehr," the claimed application of a formula in *Parker* has no "inventive concept" because "putting the formula to the side," the rest of the process was "well known"); *Parker*, 437 U.S. at 594 (holding that the claimed process is unpatentable "not because it contains a mathematical algorithm as one component, but because once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention.").

[135] According to legal realism, formalistic adjudication mechanically applies rules to facts with no concern of the purpose of the rules. *See* AMERICAN LEGAL REALISM, *supra* note 39, at xii.

[136] *See Mayo,* 132 S. Ct. at 1303. Formalistic adjudication relies on precedent even when the precedential cases have become irrelevant. *See* sources cited *supra* note 56.

[137] *See Mayo,* 132 S. Ct. at 1303.

claimed invention a law of nature without defining what a law of nature is and held the claimed invention unpatentable as such.[138]

Legal realism would demand that the courts define the concept "laws of nature" based on how this term is actually being used before applying it to adjudicate patent eligibility.[139] Scientific laws of nature are ways of organizing observed experiences.[140] By formulating the relationship between these experiences in general terms, the scientific laws provide means to control, predict, or explain a wide variety of events in different contexts.[141] Applying the laws of nature to control, predict, or explain events in the world requires bridging principles that connect the uniform and abstract terms of the laws of nature with the observable events in the world.[142] For example, the laws of physics establish how many electrons can orbit in particular shells around the nucleus, and that atoms having unfilled orbits will tend to easily give away or acquire electrons to fill up their orbits.[143] This explains why sodium reacts violently with water, because the sodium atom has a single electron in its outermost orbit that is easily given away.[144] Therefore, a scientific explanation consists of laws of nature that express relationships in general and abstract terms and bridging principles that connect these abstract terms with observable events in the world.

In the *Mayo* case, the "laws of nature" concept was assumed to have a clear meaning.[145] The claimed invention in *Mayo* was a relationship between metabolic conversion of thiopurine and drug efficacy and toxicity.[146] Viewing "laws of nature" as any relationship between measurable biological parameters, the claimed relationship in *Mayo* is indeed a "law of nature."[147] However, the claim at issue in *Mayo* describes a specific range of observed metabolite concentrations that can be used to predict efficacy and toxicity of a specific drug, and

[138] *Id.* at 1305.

[139] *Cf.* Felix Cohen, *Transcendental Nonsense and the Functional Approach*, 35 COLUM. L. REV. 809, 821 (proposing the "functional approach" that requires that legal concepts are defined in a way they are actually used in contrast to mechanically applying legal concepts).

[140] *E.g.* ERNEST NAGEL, THE STRUCTURE OF SCIENCE 4 (1961).

[141] *Id.*

[142] *See* CARL HEMPEL, PHILOSOPHY OF NATURAL SCIENCE 72–73 (Elizabeth Beardsley & Monroe Beardsley eds., Prentice Hall 1966).

[143] *See e.g.,* STEVEN S. ZUMDAHL, CHEMICAL PRINCIPLES 556 (D.C. Heath and Co. 1995) ("It is the number and type of valence electrons that primarily determine an atom's chemistry").

[144] *Id.* at 558.

[145] *Mayo*, 132 S. Ct. at 1303.

[146] *Id.* at 1291.

[147] *Id.* at 1296.

this is technology developed by clinical labs and not a law of nature like $E=mc^2$.[148] Therefore, the subject matter of this correlation is not a scientific discovery because it was generated from known facts to provide the material advantage of determining optimal drug administration;[149] and therefore, the claimed correlation in *Mayo* is a patentable technological invention.[150]

Basing patent eligibility on distinguishing science and technology would reject the claim in *Ariad Pharmaceuticals, Inc. v. Eli Lilly*,[151] in which the claim was for a method to reduce NFkB activity.[152] The inventors in this case discovered a biochemical principle for how the activity of the transcription factor (a protein controlling the expression levels of specific genes) NFkB is regulated.[153] The problem of how to reduce the activity of NFkB arose because the activity of this transcription factor is too high in many human diseases, and the claimed solution was to "reduce the activity."[154] NFkB activity is regulated by numerous biochemical mechanisms that could indirectly control NFkB activity; thus, the claimed solution covers mechanisms discovered by others and many that are not yet discovered.[155] Therefore, the claimed invention is not generated from known facts, and it does not provide material and economical benefits.[156] Rather, the invention tries to claim a scientific discovery that requires the tacit knowledge of scientists to uncover.[157] Nevertheless, the district court in *Ariad* upheld the patent because the opposition did not demonstrate that the claimed mechanism actually exists in nature, but the Federal Circuit later reversed the district court, finding the claim invalid under Section 112 for being too broad.[158] The claim in *Ariad* was clearly not a technological invention, but rather a scientific discovery of a natural regulatory mechanism.

The claim in *Classen Immunotherapies, Inc. v. Biogen*[159] was also

[148] *See id.* at 1295.
[149] *See id.*
[150] *Contra id.* at 1305.
[151] Ariad Pharm. Inc., v. Eli Lilly, 598 F. 3d. 1336, 1340 (Fed. Cir. 2010).
[152] *Id.* at 1340–41.
[153] *Id.*
[154] *See id.*
[155] *See* Liou & Baltimore, *Regulation of the NF-kappa B/rel Transcription Factor and I kappa B Inhibitor System*, 5 CURRENT OPINIONS IN CELLULAR BIOLOGY 477–87 (1993) (reviewing regulatory mechanisms of NFkB).
[156] *See* Ariad Pharm. Inc. v. Eli Lilly, 560 F.3d 1366, 1372 (Fed. Cir. 2009).
[157] *Id.*
[158] The Federal Circuit later found this patent to be invalid for lack of written description, and the Court did not address the law of nature issue. *See id.* at 1376, 1380.
[159] *See* Classen Immunotherapies, Inc. v. Biogen Idec, 659 F.3d 1057, 1067–68

continued . . .

not a technological invention. The problem in *Biogen* was how to reduce incidences of chronic immune mediated disorders, and the solution was to review relevant literature for information about which immunization schedule would reduce this risk.[160] The claimed method in *Biogen* was, therefore, a general strategy for solving the problem of identifying a low risk immunization schedule, which was not an invention generated from known facts to provide material benefit.[161] This case demonstrated that an undefined broad standard such as "law of nature" validates inventions that clearly do nothing more than claim the scientific method itself.[162] Therefore, the Federal Circuit should have rejected the claim in *Biogen* because it was not for a technological invention.[163]

The use of patent subject matter restrictions like "abstract ideas" and "laws of nature" is formalistic because it results in decisions that lack a reasoned basis. Further, the above analysis demonstrates that the term "laws of nature" is not self-explanatory and that assuming the "law of nature" term has meaning results in indeterminacy.[164] Therefore, rather than using indeterminate concepts like "laws of nature," the determination of patent eligibility should be based on whether the patent claims cover technological inventions generated from facts to solve a particular problem. This approach allows patenting of diagnostic methods, like in *Mayo*, while excluding general strategies for discovery, like in *Biogen*.

B. Naturally Occurring Products

Naturally occurring products have traditionally been found to be patent eligible if the inventor isolated and purified the compound to make it "available for any use … commercially and therapeutically."[165] The Supreme Court in *Funk Bros. Seed Co. v. Kalo Inoculant Co*.,[166] however, invalidated a patent for a naturally

(Fed. Cir. 2011) (holding that using information about whether the immunization will affect the incidence of immune disorders and use the low risk immunization schedule was patent eligible subject matter).

[160] *Id.* at 1067.

[161] *See id.*

[162] *Id.*

[163] *Id*. at 1068 (holding that "the further act of immunization in accordance with a lower risk schedule" moved the "abstract […] principle to specific application.").

[164] *See* Singer, *supra* note 9 (arguing that the law and economics school is formalistic because it assumes that such terms as "transaction costs" are self-explanatory).

[165] Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (C.C.S.D.N.Y. 1911).

[166] Funk Bros. Seed Co. v. Kalo Inoculant Co., 68 S. Ct. 440 (1948).

occurring product because "[t]he qualities of these bacteria … are manifestations of laws of nature, free to all men and reserved exclusively to none."[167] This is clearly formalistic adjudication because the claimed invention was not analyzed in light of the purpose of the patent system. In *Funk Bros.* the inventor claimed "[a]n inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus Rhizobium, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific."[168] Although this claim was clearly for a product, the Court stated that the discovery that some bacterial strains can be mixed and others not was "a hitherto unknown phenomena of nature" and "[the inventor] has no claim to a monopoly of it which the law recognizes," unless the inventor applies "the law of nature to a new and useful end."[169] In the Court's analysis, the concepts of "laws of nature," "phenomenon of nature," and "products of nature" were all mixed together.[170]

The claimed invention in *Funk Bros.* was a patent eligible technological invention. In this case, the invention solved a specific industry defined problem of packaging nitrogen-fixing bacteria by selecting strains that are not mutually inhibitory; therefore, the invention is generated from known facts to provide a material and economical advantage.[171] This idea of selecting strains that don't inhibit each other is not a scientific discovery based on tacit knowledge, but a simple combination of known facts.[172] Therefore, the claim in *Funk Bros.* covered a patent eligible technological invention and not a scientific discovery.

Similarly, the claim in *Application of Bergy*[173] was a technological invention. The claim in that case was for a "man-made biologically-pure culture of a microorganism, for industrial use in manufacturing an antibiotic, whose properties were discovered by the applicant."[174] The invention was a specific solution to the industry-particular problem of making antibiotics.[175] This invention was generated from known facts about microorganisms, and it solely gave material and

[167] *Id.* at 441.
[168] *Id.* at 440 n.1.
[169] *Id.*
[170] *See id.* at 440–43.
[171] *See id.* at 441–42.
[172] *See id.*
[173] Application of Bergy, 596 F.2d 952, 964, 962 (C.C.P.A. 1979).
[174] *Id.* at 976.
[175] *Id.* at 967.

economic benefits.[176] Therefore, the patent claim was a patent eligible technological invention and not a scientific discovery that scientists could study to generate new facts.

A general rule that categorically excludes "naturally occurring products" from patenting would, however, have found the claimed microorganisms in *Application of Bergy* patent ineligible. Excluding "naturally occurring products" categorically from patentability would have created serious problems for the biotechnology industry.[177] Not only does the biotechnology industry depend on using living organisms as tools to manufacture medicines and other products, this industry also relies, to a much greater extent than other industries, on patents to get funding.[178]

Sensitive to this problem, the Supreme Court in *Diamond v. Chakrabarty*[179] held that a bacterial strain with new properties is a patent eligible composition of matter because the claimed bacteria strain has properties that are not found in nature.[180] In *Chakrabarty*, the inventor claimed a bacterial strain genetically engineered to break down multiple components of crude oil, of which no naturally occurring bacteria is capable.[181] The claimed bacteria strain was clearly a technological invention because the inventor solved a specific problem of how bacteria can be used to clean up oil spill, which is a problem defined by the relevant industry and not based on tacit knowledge.[182] This particular solution was specific for the problem provided more than a mere starting point for further research, because there are likely to be many strategies for how to clean up oil spills.[183] In addition, if the patented life form did not have any particular utility except for the functions the life form have in the wild, then this life form is not a solution to an industry-defined problem.[184] Therefore, the *Chakrabarty* Court was sensitive to the needs of the biotechnology industry while acknowledging the potential problems

[176] *Id.* at 994 (Baldwin, J., concurring).

[177] *See id.* at 974–75 ("American industry is on the threshold of a new advance in microorganisms technology").

[178] Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM L. REV. 477, 477 (2003) ("Drug development is a famously patent-sensitive field of technology.").

[179] Diamond v. Chakrabarty, 100 S. Ct. 2204, 2208 (1980).

[180] *Id.*

[181] *Id.* at 2205–06.

[182] U.S. Patent No. 3,813,316 col. 2 (filed June 7, 1972) (issued May 28, 1974).

[183] *See* Press Release, *Can bacteria combat spill disasters?,* HELMHOLTZ CENTER FOR ENVIRONMENTAL RESEARCH (Sept. 26, 2013), http://www.ufz.de/index.php?en=35343.

[184] *See* Chakrabarty*,* 100 S. Ct. at 2208 (1980).

with patenting life forms.[185]

The holding in *Chakrabarty* had great impact on the burgeoning biotechnology industry because genetically engineered bacterial strains are a key tool for this industry.[186] In contrast, a formalist approach to the patent eligibility doctrine that categorically excludes all "naturally occurring products" from patent rights would destroy the biotechnology industry.[187] So when the Supreme Court was presented with a case that displayed the underlying conflicts of the patent system clearly, the Court resorted to a realist approach that dealt directly with these conflicts.[188] Therefore, a categorical exclusion of "naturally occurring products" will not enable adjudication consistent with the conflicting policies underlying patent law.

IV. CONSEQUENCES FOR THE BIOTECHNOLOGY INDUSTRY OF A FORMALIST APPROACH TO THE PATENT ELIGIBILITY DOCTRINE

In addition to living organisms, genes and deoxyribonucleic acid ("DNA") sequences are central tools and products of the biotechnology industry.[189] DNA poses a big problem for the courts because this molecule is not easy to put into fixed boxes, and it is a central tool and source of innovation for the biotechnology industry.[190] Therefore, genes and DNA sequences have historically been considered patentable as long as the utility requirement is met.[191] However, in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*,[192] the Supreme Court held categorically that genomic DNA is not

[185] *Id.* at 2208.

[186] *Id.* at 2204.

[187] *Id.* at 2205–06, 2208.

[188] *See id.*

[189] *Biotechnology*, ENCYCLOPEDIA BRITANNICA, https://www.britannica.com/technology/biotechnology.

[190] *Compare* Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L. J. 721, 724 (1990) (arguing that "[DNA sequences are] 'manifestations of laws of nature, free to all men and reserved exclusively to none'") (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)), *and* Andrew W. Torrance, *Gene Concepts, Gene Talk, and Gene Patents*, 11 MINN. J.L. SCI. & TECH. at 191 (listing five different gene concepts and arguing that the biotechnology industry communicated the simple view of these gene concepts to the public to make genes seem more patentable), *with* Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 19, 54 (arguing that patent eligibility of genes depends on how a gene is defined).

[191] *In re* Fisher, 421 F.3d, 1365, 1371 (Fed. Cir. 2005) (holding that the claimed DNA sequences were invalid patent-eligible subject matter because the inventor failed to demonstrate an immediate use).

[192] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119–20 (2013) (holding that genomic DNA is not patent eligible subject matter

continued . . .

patentable because it is a naturally occurring product, whereas complimentary DNA (cDNA) can be patentable because it is man-made.[193] The conflicting and complicated issues underlying determining patentability of genes and DNA demands a realist approach that bases this determination on an understanding of DNA-based technology.

A. The Dramatic Development of DNA Based Technology and Diagnostics

Mendel first used the concept of genes to explain the inheritance of traits over generations.[194] Mendelian genetics consider genes units that are directly associated with a trait, which is an observable feature of an organism, like eye color.[195] But the full power of these genetic studies could not be harnessed before it was discovered that genes were made of DNA that encoded proteins.[196] These proteins perform most of the essential functions in the cells of an organism that are necessary for supporting life in addition to causing the observable features that the early geneticists were interested in.[197]

DNA provides the instructions that tell the cells how to make the proteins they need. DNA is a string of nucleotides labeled A, T, G, and C, and they form triplicate "words" that signal the incorporation of a specific amino acid into a sequence that makes up a particular protein.[198] The cells do not make proteins directly from DNA.[199] First, in a process called transcription, the cells make a copy of the relevant part of DNA called RNA.[200] Second, before the nucleotide sequence can be translated into proteins, the RNA must undergo a process called splicing, which fuses together the protein coding

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because it is a naturally occurring product).

[193] *Id.* at 2119.

[194] *See, e.g.,* PAUL GRIFFITHS & KAROLA STOTZ, GENETICS AND PHILOSOPHY: AN INTRODUCTION 9 (4th ed. 2013) (According to Mendelian inheritance theory "each organism contains two factors that determine which character it will display. One factor comes from each parent, and if an organism inherits two different factors, one is always expressed preferentially over the other.").

[195] *Id.* at 9.

[196] *Id.* at 34 ("Molecular biology was born when geneticists, no longer satisfied with a quasi-abstract view of the role of genes, focused on the problem of the nature of genes and their mechanism of action.") (citing MICHEL MORANGE, *A HISTORY OF MOLECULAR BIOLOGY* 2, (Matthew Cobb trans., 2000)).

[197] BRUCE ALBERTS ET AL., THE CELL 4–12 (Garland Science 4th ed. 2002).

[198] *Id.*

[199] *Id.*

[200] *Id.*

sequences called exons.[201] In most genes, but not all, the exons are separated by non-coding sequences called introns, and splicing is necessary to make one continuous instruction for making the desired protein.[202] Finally, the spliced mRNA is translated into protein.[203] Transcription, splicing, and translation are all regulated by complex mechanisms initiated by regulatory sequences in DNA.

These regulatory sequences are located in the non-coding regions of DNA, and they function to control the activity and the responsiveness of genes to the environment, creating a gene expression pattern that defines the identity of the distinct cell types that make up the living organism.[204] The genome responds to these signals by regulating the process of transcription, splicing, and translation to make proteins in the appropriate quantities, at the right time and place.[205] This tight control ensures that the proteins are not only made, but can be organized in a particular manner that is necessary for the living organisms' functions and properties.[206]

The reactivity of the genome to the environment and intracellular events is controlled and limited by mechanisms regulating the three-dimensional structure of DNA.[207] DNA is wrapped around proteins called histones.[208] The tightness of this DNA wrapping provides physical restraints on gene expression.[209] A gene positioned in a part of the DNA that is tightly wrapped makes the gene inaccessible for transcription, and therefore, the cells can exclude large portions of the genome from being expressed while allowing expression of other genes.[210] These repressed areas of the genome can be preserved across cell generation to maintain the identity of particular cells and tissues.[211]

The restraining of the genome to protect the cellular identity is controlled by epigenetic mechanisms that make subtle modifications

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[201] *Id.*

[202] *Id.* at 317.

[203] *Id.* at 318.

[204] Evelyn Fox Keller, *From Gene Action to Reactive Genomes*, 592 J. PHYSIOLOGY 2423, 2425 (2014).

[205] *Id.* at 2427.

[206] *Id.*

[207] Mark Blaxter, *Revealing the Dark Matter of the Genome*, 330 SCI. 1758 (2010).

[208] *Id.*

[209] Keller, *supra* note 204, at 2427.

[210] *Id.*

[211] *See, e.g.,* Raphael Margueron & Danny Reinberg, *Chromatin Structure and the Inheritance of Epigenetic Information*, 11 NATURE REV. GENETICS 285–96 (2010) (reviewing current understanding of how chromatin structure can convey epigenetic information across cellular generations).

of the histones and the DNA.[212] These chemical modifications tell the cells how tightly to pack the particular region of DNA, and they are called epigenetic (or beyond genetics) modifications because they also can be preserved across cellular generations.[213] The enzymes performing these modifications can in some instances be connected to extra-cellular signals, so cellular communication can change the structure of DNA, and therefore, the reactivity of the genome.[214] The function of this mechanism is to remember the ephemeral signals, much like you would have to remember a text message if it is instantly deleted upon reading it.[215] The cells use epigenetic mechanisms to write down these transient messages, and this will affect the cells' future behavior, development, and response to the environment.[216] Therefore, the subtle chemical modifications of histones and DNA can have dramatic consequences for whether a gene is expressed in a particular cell type and how a particular cell type will react to a given outside signal.[217]

The discovery of the reactive genome has expanded the scope of medical research.[218] Human disease is not only caused by changes in DNA sequences that causes the production of a dysfunctional protein, but also changes in the non-coding part of the genome can cause pathological changes by influencing the regulation of protein production or how the genome interacts with the environment.[219] Armed with this recent discovery of the reactive genome, scientists are now finding new ways of diagnosing and treating diseases that depend on using the non-coding regions of the genome.[220]

B. The Patent Eligibility of DNA Based Technology

The current patent eligibility doctrine fails to recognize that

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[212] *Id.* at 285.

[213] *Id.* at 286.

[214] *See, e.g.,* Øyvind Dahle *et al.*, *Nodal Signaling Recruits the Histone Demethylase Jmjd3 to Counteract Polycomb-Mediated Repression at Target Genes*, 3 SCI. SIGNAL 1, 1 (2010) (establishing a direct link between a developmental signaling pathway and the epigenetic regulator called Polycomb); *see generally* Helai P. Mohammed & Stephen Baylin, *Linking Cell Signaling and the Epigenetic Machinery* 28 NATURE BIOTECH. 1033, 1033–38 (2010) (reviewing current understanding of how cellular communication is linked to epigenetics).

[215] Margueron, *supra* note 211, at 286.

[216] Dahle, *supra* note 214.

[217] *Id.*

[218] Elizabeth Pennisi, *ENCODE Project Writes Eulogy for Junk DNA*, 337 SCI. 1159, 1159–61 (2012).

[219] *Id.* at 1159.

[220] *Id.* at 1161.

diagnostic methods utilizing genetic knowledge are technological innovations and not scientific discoveries. The Supreme Court held in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*[221] that genomic DNA is patent ineligible because it is a naturally occurring product; whereas cDNA is patent eligible because it is not naturally occurring.[222] The Court argued that cDNA is different from genomic DNA because cDNA lacks introns and is, therefore, distinct from the naturally occurring DNA.[223] It is correct that cDNA will generally not contain introns because it is copied from mRNA, and the majority of mRNA has indeed undergone splicing that removes the introns.[224] However, this distinction is otherwise inaccurate for numerous reasons. First, many naturally occurring genes do not contain introns.[225] Second, when cDNA is made from the RNA pooled from cells, it is made from both unspliced and spliced RNA, resulting in cDNA with introns, and it is not clear if this intron containing cDNA can be patented.[226] Finally, it is also not clear if Expressed Sequence Tags, which are cDNA fragments held patent eligible in *Fisher*,[227] are eligible under *Myriad* because this cDNA is identical to naturally occurring sequences.[228] Thus, the Court's ruling in *Myriad* is formalistic because it relies on the indeterminate distinction between cDNA and genomic DNA.

The claimed genomic DNA for the BRCA1/2 genes in *Myriad* is a technological invention and patent eligible subject matter. In *Myriad*, the patent owners merely optimized the known association between the BRCA1/2 genomic region and breast cancer to diagnose the disease.[229] Scientific discoveries that can generate new methods in breast cancer diagnosis will not come from sequencing the BRCA1/2 genes or otherwise using these genes.[230] Rather, scientific progress will come from either identifying other genes that can serve as diagnostic markers for breast cancer or from genome wide association

[221] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119 (2013) (holding that genomic DNA is not patent eligible subject matter because it is a naturally occurring product).

[222] *Id.*

[223] *Id.* at 2109.

[224] *Id.* at 2112–15.

[225] Ass'n for Molecular Pathology v. U.S.P.T.O., 689 F.3d 1303, 1329 (Fed. Cir. 2012).

[226] *See generally* Ass'n for Molecular Pathology v. U.S.P.T.O., 653 F.3d 1329 (Fed. Cir. 2011).

[227] *In re* Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

[228] *Myriad Genetics*, 133 S. Ct. at 2119.

[229] *Id.* at 2112.

[230] Shany Koren & Mohamed Bentires-Alj, *Breast Tumor Heterogeneity: Source of Fitness, Hurdle for Therapy*, 60 MOLECULAR CELL 537, 539–40 (2015).

studies that seek to identify numerous genetic as well as epigenetic changes in the pathologic cells.[231]

Preventing patents on non-coding genomic DNA will be a problem for genome-wide association technology since ninety percent of DNA changes are found nowhere near protein-coding regions.[232] Identification of new and better diagnostic methods will, therefore, require scientific discoveries of new associations between genomic DNA regions and human diseases, and then technological developments from these new facts.[233] These technological developments deserve patent protection to ensure the recovery of resulting costs, considering that patenting these technological inventions will not impede the upstream of scientific discoveries.[234] Therefore, whether a claim of DNA is patent eligible should depend on whether the claim is a technological invention or a scientific discovery rather than formalistically excluding genomic DNA from patenting.

Patenting diagnostic methods using genomic DNA has also been held patent ineligible under the laws of nature exception.[235] In *Ariosa*,[236] the court held that a method to diagnose fetuses by identifying cell-free fetal DNA ("cffDNA") in the blood samples from the pregnant woman did not infringe on the patent, because the patent was directed at patent-ineligible laws of nature and phenomenon.[237] This discovery provides a novel, non-invasive method to diagnose the fetus that avoids the risks of alternative methods, and this method is considered a significant breakthrough in the field.[238] Nevertheless, the Federal Circuit invalidated this patent under *Mayo* because the presence of cffDNA in the blood is directed to a patent ineligible subject matter, and the inventor did not add an inventive step.[239]

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[231] *See generally id.* (reviewing the heterogeneity of breast tumors and the need for prognostic and predictive biomarkers to provide efficient treatment); *see generally* Peter M. Visscher *et al., Five Years of GWAS Discovery,* 90 AM. J. HUM. GENETICS 7 (2012) (reviewing studies of single nucleotide polymorphisms variations in human autoimmune diseases and concluding that ninety percent of these polymorphisms were in non-coding regions).

[232] *Visscher, supra* note 231*,* at 11.

[233] *Id.* at 19.

[234] Koren & Bentires-Alj, *supra*, note 230, at 542.

[235] Mayo Collaborative Servs. v. Prometheus Labs., 132 S. Ct. 1289, 1291 (2012).

[236] Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F. 3d 1371 (Fed. Cir. 2015).

[237] *Id.*

[238] YM Dennis Lo, *Presence of Fetal DNA in Maternal Plasma and Serum*, 350 LANCET 485, 485 (1997) (this article by Drs. Lo & Wainscoat has been cited as of present date 186 times).

[239] *Ariosa Diagnostics*, 788 F.3d. at 1380.

The Federal Circuit was bound by the "sweeping language of the test set out in *Mayo Collaborative Services v. Prometheus Laboratories* … ."[240] Judge Linn continued, "[t]his case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain."[241] Therefore, the use of categorical rules established in *Mayo* has resulted in that a "meritorious invention"[242] is not patent eligible, and this formalistic approach will cause similar problems in the future.

The realist approach adopted herein would rescue diagnostic methods from ineligibility. The problem in *Ariosa* is how to diagnose a fetus by non-invasive methods; the claimed invention solved this problem.[243] When viewed as a whole, the claimed invention is limited to the method of using cffDNA to diagnose a pregnant woman for pre-eclampsia.[244] Patenting a method of using cffDNA to diagnose pre-eclampsia will not preclude other scientists from finding alternative uses for cffDNA because the patent is for a method and not the cffDNA itself.[245] This diagnostic method is, therefore, a technological invention because it is generated from already known facts and because it provides material and economical benefits. A patent on the cffDNA itself, however, would be for a scientific discovery because studying this material will generate new knowledge. Furthermore, this originality will require the tacit knowledge of a scientist to generate, and not mere technological application of known facts.

The patent in *Genetic Technologies Ltd. v. Merial LLC*[246] is distinct from *Ariosa* and exemplifies claiming a scientific discovery and not the technological application of known facts. In *Genetic Technologies*, the Federal Circuit correctly found that the patent at issue covered "essentially all applications, via standard experimental techniques, of the law of linkage disequilibrium to the problem of detecting coding sequences of DNA."[247] The named inventor of the patent at issue in *Genetic Technologies* discovered that coding and non-coding regions could sometimes link together, a phenomenon called linkage disequilibrium, and that this phenomenon can be used to diagnose diseases by amplifying non-coding regions and identify the

[240] *Id.*
[241] *Id.*
[242] *Id.*
[243] *Id.* at 1381.
[244] *Id.*
[245] *Id.* at 1378.
[246] Genetic Techs. Ltd. v. Merial LLC, 818 F.3d 1369 (Fed. Cir. 2016).
[247] *Id.* at 1375.

linked coding regions.[248] For example, analysis of the HLA haplotype genes is a well-established technology for diagnosis of diseases.[249] As in *Ariosa*, a specific application of linkage disequilibrium to diagnose a particular disease should be a patent eligible technology, but the patent in *Genetic Technologies* claims broadly any linkage between coding and non-coding regions without reference to a particular genetic disease.[250] Therefore, this patent would cover yet to be discovered genomic disequilibrium linkages that can be used for diagnosis, and the patent rests on the "newly discovered natural law of linkage disequilibrium between coding and non-coding regions and adds little more than a restatement of the natural law itself."[251] This use of the law of nature exemption to find the claims in *Genetic Technologies* invalid under Section 101 caused the Court to fail to recognize that in *Ariosa*, the patent at issue was limited to a method of diagnosing a particular disease, leaving others free to develop other uses of cffDNA detection and the cffDNA itself.[252] Invalidating the patent in *Genetic Technologies* based on a distinction between science and technology would distinguish *Ariosa* and *Genetic Technologies*, and thus, would allow patenting of specific diagnostic methods of a particular disease while preventing patenting of general approaches to discovering diagnostic methods.

Basing Section 101 on distinguishing science and technology would also reconcile *Ariosa* and *Rapid Litigation Management v. CellzDirect, Inc.*[253] In *CellzDirect,* the named inventor of the patent at issue had discovered that multiple rounds of freezing and thawing some hepatocytes did not actually damage the cells, in contrast to the prior common belief that this cryopreservation process would require the cells' destruction if not used immediately; therefore, the Federal Circuit found that this new method was patent eligible.[254] Indeed, improving cryopreservation is a technological development of a method that solves a particular well-defined problem and should be

[248] *Id.*

[249] Bengt O. Bengtsson & Glenys Thomson, *Measuring the Strength of Associations Between HLA Antigens and Diseases*, 18 TISSUE ANTIGENS 356–63 (1981).

[250] *Genetic Techs.*, 818 F.3d 1369, 1372.

[251] *Id.* at 1380.

[252] *See id.* at 1376 (holding that the *Genetic Technologies* patent is invalid for claiming a law of nature because "[T]he similarity of claim one to the claims evaluated in *Mayo* and *Ariosa* requires the conclusion that claim one is directed to a law of nature.").

[253] *See id.;* Rapid Litig. Mgmt. v. CellzDirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016).

[254] *CellzDirect,* 827 F.3d at 1045.

patentable as such.[255] However, the Federal Circuit cannot make it clear why this method of cryopreservation is patent eligible, and the method of diagnosing preeclampsia in *Ariosa* is not.[256] The Federal Circuit states that the process claims in *Ariosa* were directed to patent ineligible cffDNA itself,[257] which is a circular argument. In addition, the *CellzDirect* Court does not explain why a process using, but not claiming, naturally occurring cffDNA is patent ineligible; whereas, a process directed to naturally occurring cells is patent eligible. In contrast, basing Section 101 subject matter eligibility on distinguishing technology and science would find that both an improved method of cryopreservation and a novel method for preeclampsia diagnosis are patent eligible technologies.

None of the theories underlying Section 101—pre-emption, over-rewarding, innovation-harm, or non-economic goals—appears to suggest that diagnostics are unpatentable.[258] Patenting diagnostic methods will not hinder scientific progress, since diagnostic innovation is a technology generated from known facts and not scientific discoveries that generate new facts. Diagnostics is also a technology that requires the resources of the pharmaceutical industry to optimize and standardize the method until it is suitable for clinical purposes.[259] The patent system is uniquely suited to reward the necessary investment in time and money to develop diagnostics; whereas science, with its focus on generating novel discoveries and with publishing as the ultimate goal, is unlikely to support the development of diagnostics. Therefore, excluding diagnostics from

[255] *Id.* at 1048 (quoting Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354 (2014)).

[256] Alice O. Martin, *Impact of the Federal Circuit Decision in Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc. on 35 U.S.C. § 101 Rejections*, AM. INTELL. PROP. L. ASSOC. (July 2016), http://www.aipla.org/committees/committee_pages/Biotechnology/diagnostics/Shared%20Documents/Diagnostics_Buzz_201607b.pdf.

[257] *CellzDirect,* 827 F.3d at 1048.

[258] *See* J. Jonas Anderson, *Applying Patent-Eligible Subject Matter Restrictions*, 17 VAND. J. ENT. & TECH. L. 267, 287–92 (2015) (establishing four theories underlying Section 101: pre-emption, over-rewarding innovation, preventing innovation harm, and non-economic goals).

[259] Samantha Kulkarni et al., *The Outlook for Personalized Medicine*, *in* PERSONALIZED MEDICINE: THE PATH Forward 2 (McKinsey & Co. ed., 2013) ("[T]he use of advanced diagnostics for therapy selection will have exponential growth. . . [G]rowth is likely to accelerate as nearly half of the pre-clinical and Phase 1 assets in the pharma pipeline have associated diagnostics."). *See e.g.*, *Pharma & Diagnostics- Enhance your Studies*, EUROFINS GENOMICS, https://www.eurofinsgenomics.eu/en/markets/pharma-diagnostics.aspx (last visited Sept. 29, 2016 5:30 PM) (illustrating a companion diagnostic program for pharmaceuticals).

patenting is contrary to the purpose of the patent system and its underlying theories.[260]

To save diagnostic methods from being barred from patenting, the Court should adopt a more flexible realist approach to Section 101 in place of categorically determining the boundaries between eligible and ineligible subject matter. Given that the Supreme Court declined to hear *Ariosa*,[261] the Section 101 jurisprudence established by *Myriad* and *Mayo* remains as controlling law. The courts can, however, use legal realism in place of formalism when applying *Myriad* and *Mayo* to new technologies to ensure that "meritorious inventions" are granted patent protection.

V. CONCLUSION

The challenge facing the patent eligibility doctrine to simultaneously provide predictability of adjudication and flexibility to meet the dynamic changes of the real world is central to the law. Meeting this challenge gave rise to the formalist and realist approaches to legal thought.[262] Formalism and realism can, therefore, inform the development of the patent eligibility doctrine. The natural sciences also face the challenge of preserving the system and changing the rules when forced to by new realities. When new discoveries and technologies challenge the existing worldview, the scientific community must decide whether novel discoveries can be incorporated in the existing corpus of science, or whether these novelties demand a paradigm shift that changes the whole system.[263] Thus, science and legal philosophy have much to learn from each other's struggle with the conflict between conserving a predictable system of rules and ensuring that the system is in tune with reality. An integration of science and law can, therefore, benefit legal thought in general, as well as informing the patent eligibility doctrine.

The Supreme Court's formalistic approach to the patent eligibility doctrine is clearly not in tune with reality and has led to the exclusion of diagnostic methods from patentability, even though diagnostic methods are clearly technological inventions. Given the undesirable consequences of the current patent eligibility doctrine, the formalistic approach to exclude patents claiming "laws of nature" and "naturally occurring products" should be restricted by legal realism. Rather than limiting adjudication of Section 101 to defining the boundaries of

[260] *Anderson, supra* note 258.
[261] Sequenom, Inc. v. Ariosa Diagnostics, Inc., 136 S. Ct. 2511 (2016).
[262] *See supra* Section I.B.
[263] *See supra* Section I.D.

subject matter exceptions, judges should be more like Heidegger's cabinetmakers and engage with the material to find the balance between rewarding innovation and protecting the sources of creativity. This Note argues that a patent eligibility doctrine that broadly allows patenting inventions that are generated from known facts and that give economical advantages will sufficiently avoid harming scientific progress that emerges from tacit knowledge. This legal realist approach can generate further rationales for patentability that get their gravitational pull from the ultimate purpose of the patent system: "[T]o promote the Progress of Science and useful Arts… ."[264]

[264] U.S. CONST. art. I, § 8, cl. 8.