

From: Efthimios Parasidis [e-mail redacted]
Sent: Thursday, September 23, 2010 1:55 AM
To: Bilski_Guidance
Subject: Proposal for subject matter framework

Dear Sir or Madam,

I write to you in response to the request for comments for guidance on establishing a new framework for subject matter eligibility following the Supreme Court's Bilski decision. The attached draft article not only proposes a practical and theoretically sound method for analyzing process claims under Section 101, it sets forth a uniform framework for determining patent-eligible subject matter that is accurately grounded in historical context and technology-agnostic in construction and application. The framework is succinctly summarized in Appendix A of the article in a decision-tree format, which is a format frequently utilized by the USPTO in setting forth guidelines for determining eligible subject matter.

It is my sincere hope that the attached article assists the Patent Office in structuring guidelines in this area of patent law. Please feel free to utilize any or all sections of the article - all I ask is that you cite to this article as a source for the USPTO's guidelines. The article is scheduled for publication in Dec 2010, and may be available in final form prior to that time.

Please feel free to contact me should you have any questions regarding my proposal.

Very truly yours,
Efthimios Parasidis

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A UNIFORM FRAMEWORK FOR PATENT ELIGIBILITY

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ABSTRACT

Patent doctrine has been plagued by a prolonged state of ambiguity. As a number of recent cases highlight, there remains a need to clarify patent law so as to permit resolution of its most fundamental question – clear identification of the categories of subject matter that are eligible for patent protection. Coupled with the active role the Supreme Court has taken in examining this precise issue, individuals and non-profit organizations have galvanized a public discourse through constitutional challenges to the issuance of various biotechnology patents. Although the statutory framework governing patent-eligible subject matter has remained constant since 1793, courts have been unable to create a comprehensive test for determining patent-eligible subject matter that accurately embodies the foundational principles that underlie the federal grant of patents. I argue that the proximate cause of the lack of an adequate framework is the failure of courts to clearly define the statutory categories and the absence of a technology-agnostic method of analyzing whether an invention claims ownership over a product of nature. This Article sets forth a uniform framework that addresses patent-eligible subject matter through the creation of a practical methodology that focuses on these two principles. The advantages of the proposed framework are highlighted through the application of the framework to traditional inventions and emerging biotechnologies.

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INTRODUCTION

The classic tale is one that perhaps is more indicative of human nature than any limitation of the doctrine under which its flourishing persists. In one representation, a researcher uncovers a natural principle long outside the bounds of human knowledge. In another, a creative mind formulates a new process applicable to distinct endeavors. In exchange for disclosing their work product to the public, both seek ownership over their innovation to fullest extent of the law. For each, the question becomes whether, and to what extent, the patent laws afford a cognizable property interest.

The Supreme Court has recently taken an active role in examining the scope of subject matter that is eligible for patent protection.¹ Coupled with the

¹ In June 2010, the Court indicated that business method patents are not categorically excluded from patent-eligible subject matter. *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218 (2010) (affirming invalidity of patent-at-issue, but reversing the Federal Circuit's establishment of the machine-or-transformation test as the exclusive test for process claims). Despite concurring in the judgment, four Justices argued in favor of a wholesale prohibition. *Id.* at 3231. A few years earlier, the Court granted certiorari in a patent infringement case involving biomarkers, where the sole issue was whether a method of testing for a vitamin deficiency constitutes patent-eligible subject matter. *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006) (hereinafter *LabCorp*). Although *LabCorp* was dismissed as being improvidently granted, three Justices dissented from the dismissal and challenged the patentability of the biomarker claim. *Id.* at 125. See *infra* Part IV.C for a detailed analysis of *LabCorp*. Four years later, in June 2010, the Court granted certiorari to a second biomarker case where the patent-at-issue centers on a method of treating a patient with a gastrointestinal disorder. *Mayo v. Prometheus Labs*, 561 U.S. __ (June 29, 2010).

high Court's review, individuals and non-profit organizations have galvanized a public discourse through constitutional challenges to the issuance of various biotechnology patents.² Although the statutory framework governing patent-eligible subject matter has remained constant since 1793, courts have been unable to create a comprehensive test for determining patent-eligible subject matter that accurately embodies the legislative intent and constitutional mandate underlying the patent laws and is applicable across all technologies.³ The goal of this Article is to set forth such a dynamic framework.

Following the grant, the Court remanded the case to the Federal Circuit for review in light of its *Bilski* ruling. *Id.* The same day, the Court granted certiorari in *Classen v. Biogen*, 561 U.S. __ (June 29, 2010), and remanded to the Federal Circuit for review in light of *Bilski*. The issue in *Classen* is whether patent-eligible subject matter extends to a method of determining whether an immunization schedule is effective in treating a particular disease. *Classen v. Biogen*, 178 Fed. Appx. 14 (Fed. Cir. Apr. 10, 2006).

² In May 2009, the ACLU and Public Patent Foundation took the lead in filing challenges to numerous gene patents owned by Myriad Genetics. See *Association for Molecular Pathology v. United States Patent and Trademark Office*, __ F. Supp. 2d __, 2010 WL 1233416 (S.D.N.Y. April 5, 2010). The patents cover genes associated with breast and ovarian cancer, and include claims relating to methods of testing for the presence of the genes, correlations between presence of the genes and the likelihood of developing cancer, and copies of the gene sequences themselves. The case immediately gained significant public attention, reinvigorating the debate regarding legal and ethical issues associated with gene patents. Less than one year after the complaint was filed, on March 29, 2010, the court granted summary judgment in favor of plaintiffs. In a 156-page opinion, Judge Sweet held that the product claims constitute unpatentable subject matter pursuant to the product of nature doctrine, finding the claimed DNA sequences to not be "markedly different" from sequences found in nature. *Molecular Pathology*, 2010 WL 1233416, at *46. Likewise, numerous process claims were invalidated on the grounds that they recited a property interest in an abstract idea or mental process. *Id.* at *46-50. The invalidation of the claims is significant insofar as approximately 20% of human genes are patented, including genes that are associated with forms of cancer, Alzheimer's and other diseases. In addition to the gene patent case, in April 2010, the USPTO issued an office action invalidating various stem cell patents held by the Wisconsin Alumni Research Foundation ("WARF"), a non-profit arm of the University of Wisconsin. The challenge was raised by the Public Patent Foundation and the Foundation for Taxpayer and Consumer Rights. See *Two Groups Try for Revocation of Human Embryonic Stem Cell Patents*, 25 *Biotechnology L. Report* 555 (Oct. 2006). See *infra* Part IV.D for further discussion of this proceeding.

³ See John F. Duffy, *Rules and Standards at the Forefront of Patentability*, 51 *WM. & MARY L. REV.* 609 (2009) (for detailed discussion of the repeated failure of court-constructed rules regarding patent-eligible subject matter); Alan Durham, *Natural Laws and Inevitable Infringement*, 93 *MINN. L. REV.* 933, 977 (2009) (highlighting the lack of a uniform framework and calling for "urgent work to be done" in this area); Rebecca Eisenberg, *Re-examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 *EMORY L.J.* 783, 785 (2000) (noting that there is "profound uncertainty" in applying patent doctrine to determinations of patentable subject matter).

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A judicious analysis of patent jurisprudence reveals a two-step method for determining patent-eligible subject matter: an invention is patent-eligible if (i) it corresponds to a statutory category outlined in Section 101 of the Patent Act, which include processes, machines, manufactures or compositions of matter,⁴ and (ii) does not violate the product of nature doctrine, which precludes eligibility for laws of nature, natural phenomenon, mental processes and abstract ideas.⁵ Rather than establishing a framework that is solely grounded upon these principles, decisions have primarily been guided by intuition and analogy, and have often comingled analysis of subject matter eligibility with other statutory requirements.⁶ Though a plethora of eligibility tests has resulted,⁷ each test has produced inconsistent results when applied across a diverse range of technologies.⁸

Admittedly, there is an epistemological conundrum in identifying what, precisely, *is* a product of nature. Classifying some inventions as products of nature, and imposing special legal rules as a result of that classification, implies that patent protection should be afforded solely to inventions that are products of something-other-than-nature. At a fundamental level, however, all

⁴ 35 U.S.C. § 101 (2010).

⁵ *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

⁶ See, e.g., *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (describing the product of nature doctrine by listing examples of inventions that are patent-ineligible subject matter); *Chakrabarty*, 447 U.S. at 309 (same). As a review of the historical record reveals, this *ad hoc* approach has proved to be both inefficient and unreliable. See *infra* Part II. Given emerging biotechnological advancements and a general lack of understanding of science on the part of the judiciary, a systematic and technology-agnostic framework is essential to furthering the public policy underlying the patent statute and maintaining a reliable patent system. For example, questions raised by the judiciary during oral argument in both the *Bilski* and *Molecular Pathology* cases reveal a lack of understanding of patent doctrine and the role of subject matter eligibility in the statutory framework. Given the “confused and inconsistent jurisprudence” surrounding patent-eligible subject matter, some have advocated for wholesale elimination of judicial subject matter requirements. See, e.g., Michael Risch, *Everything is Patentable*, 75 TENN. L. REV. 561 (2008). This Article proposes an alternative approach to conceptualizing patent-eligible subject matter, and a systematic method of translating the theory into practice.

⁷ For example, the machine-or-transformation test is the third attempt in three decades to set forth a comprehensive test for analyzing subject matter eligibility for process claims. See Duffy, *supra* note __, at 612. Tests that survive half the life of a patent do not instill confidence in the patent system. *Id.* See also *Festo Corp v. Shiketsu Kinzoku Kabushiki Co.*, 535 U.S. 722, 739 (2002) (fundamental alterations in patent laws risk destroying the legitimate expectations of inventors in their property).

⁸ This is significant, insofar as international treaties, of which the United States is a signatory, prohibit member states from enforcing patent laws that disproportionately impact certain technology sectors. TRIPS Article 27(1).

things may be properly classified as products of nature.⁹ In addition, patents that implicate the product of nature doctrine often relate to emerging technologies where bioethical debate of the underlying invention may overshadow analysis of the precise subject matter sought to be patented.¹⁰ Although patent doctrine reflects a morality view underlying the Intellectual Property Clause of the U.S. Constitution,¹¹ since the patent laws do not identify morality as a component of the subject matter calculus,¹² discussion of the moral implications of a particular invention is improper and unnecessarily complicates the legal analysis.¹³

⁹ As a prominent patent attorney and scholar from the nineteenth century explains, “in every form in which matter is used, in every production of the ingenuity of man, he relies upon the laws of nature and the properties of matter, and seeks for new effects and results through their agency and aid.” George Ticknor Curtis, *A TREATISE ON THE LAW OF PATENTS* (2d ed. 1854), at 8. Nearly 100 years after Mr. Curtis’s observation, Justice Frankfurter provides a similar analysis, stating that “everything that happens may be deemed ‘the work of nature,’ and any patentable composite exemplifies in its properties ‘the laws of nature.’” *Funk Brothers Seed v. Kalo Inoculant*, 333 U.S. 127, 134-135 (1948) (Frankfurter, concurring). For Justice Frankfurter, “arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.” *Id.* at 135. See also *LabCorp*, 548 U.S. at 134 (highlighting the difficulty in delineating the boundaries of the product of nature categories).

¹⁰ For instance, in the *Myriad* case, the court repeatedly highlights the ethical concerns raised by the issuance of gene patents. *Molecular Pathology*, 2010 WL 1233416, at *9, *18-21, *24-27, and *36.

¹¹ As scholars have noted, Locke’s philosophy has played an integral role in the development of the intellectual property laws in the United States. See, e.g., Justin Hughes, *The Philosophy of Intellectual Property*, 77 *Georgetown L.J.* 287, 296-299 (1988). For Locke, the world is a universal common in which all individuals possess an equal right. John Locke, *TWO TREATISES ON GOVERNMENT* (1698). An exception to this rule lies in the body of each individual, over which each individual enjoys a property right. *Id.* This individual property right not only extends to one’s person, it encompasses the labor of one’s body and the work of one’s hands. *Id.* One significant condition qualifies this extension to labor-based property rights – whenever an individual removes something from the common, with respect to the thing removed, there must remain enough of the thing, and the thing as good as it was, in the common for others to freely use. *Id.* Coupled with Locke’s natural rights justification for intellectual property protection, U.S. patent doctrine is grounded on utilitarian principles. See generally Landes & Posner, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* (2003). Namely, the patent laws are structured such that they stimulate investment and provide economic incentives to invent through grants of limited monopolies.. See *id.*

¹² For many years, the judicially-created moral utility doctrine served as a gatekeeper for patent-eligible subject matter. See Margo Bagley, *Patent First, Ask Question Later: Morality and Biotechnology in Patent Law*, 45 *WM. & MARY L. REV.* 469 (2003). This doctrine, however, is currently untended. *Id.*

¹³ This is not to say that moral considerations play no role in determining patent-eligible subject matter. Rather, relying on moral convictions should be limited to structuring a

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In the aggregate, the failure to adequately define the categories that are encompassed by the product of nature doctrine has led to uncertainty as to the scope of subject matter that is *ineligible* for patent protection.¹⁴ This is problematic, since investments are largely driven by valuations of intellectual property rights and research dollars are primarily allocated to those innovations that have, or show promise for, patent protection.¹⁵ As scholars and jurists have often noted, ambiguity as to the scope of patent protection significantly hinders innovation and negatively impacts the stream of commerce.¹⁶

I argue that the proximate cause of the lack of a uniform framework is the failure of courts to properly define the statutory categories and the absence of a systematic and technology-agnostic method of analyzing whether an invention claims ownership over a product of nature. This Article establishes a new framework that addresses patent-eligible subject matter through a practical methodology that focuses on these two principles. Upon examining the theoretical foundation surrounding subject matter jurisprudence and defining the four statutory categories of eligible subject matter, I set forth a decision tree format for analyzing whether a patent claim implicates the product of

framework for patent eligibility. See, e.g., Ronald Dworkin, *The Temptation of Elena Kagan*, *The New York Review* at 36 (Aug. 19, 2010) (arguing that judges “must rely on moral convictions” in order to unravel meaning from legislative history). Pursuant to the patent statute of the United States, however, examining the moral implications of individual inventions is contrary to the language of the statute. Compare with the European framework, which precludes subject matter eligibility to inventions that offend the public morality. European Patent Convention Article 53(a). See Bahadur and Morrison, *Patenting human pluripotent cells: balancing commercial, academic and ethical issues*, 25 *Human Reproduction* 14, 16 (2010) (highlighting this distinction through use of the WARF patents as a paradigm). In the United States, ethically undesirable outcomes are addressed through provisions that are outside the scope of patent law *per se*. *Id.*

¹⁴ For example, as Justice Stevens notes in the recent *Bilski* opinion, the Court has yet to provide “a satisfying account of what constitutes an unpatentable abstract idea.” *Bilski*, 130 S. Ct. at 3236 (Stevens, concurring in judgment). See also *LabCorp*, 548 U.S. at 134 (the product of nature categories are “not easy to define”).

¹⁵ See, e.g., *LabCorp*, 548 U.S. at 138. As Judge Newman has noted, significant or frequent changes to patent doctrine undermine the legitimacy of the patent laws and are detrimental to individuals and businesses that rely upon the patent laws for investment decisions. *In re Bilski*, 545 F.3d 943, 992 (Fed. Cir. 2008) (Newman, dissenting).

¹⁶ See, e.g., *id.*; Duffy, *supra* note __, at 611; *Bilski*, 130 S. Ct. at 3231 (Stevens, concurring) (“In the area of patents, it is especially important that the law remain stable and clear.”); *Bilski*, 130 S. Ct. at 3258 (Breyer, concurring in the judgment) (noting the “need for clarity and settled law” in the area of patent-eligible subject matter); *LabCorp*, 548 U.S. at 138 (describing the legal uncertainty in the area of biomarker patents which, in turn, directly hinders the practice of medicine).

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nature doctrine.¹⁷ Specifically, for each product of nature category, a series of questions is proposed.¹⁸ The questions are structured so as to embody Supreme Court interpretation of the fundamental principles underlying the exclusion of products of nature from patent-eligible subject matter. The advantages of this methodological approach are highlighted through the application of the new framework to traditional inventions and emerging biotechnologies.

Part I briefly examines the development of Section 101 of the patent statute. With an eye towards uncovering the principles underlying each product of nature category, Part II takes a detailed look at the evolution of product of nature jurisprudence and provides a formative analysis of seminal cases. Part III sets out a uniform framework for determining patent-eligible subject matter by accurately defining the statutory categories and establishing a methodological approach to delineating exceptions to patent-eligible subject matter pursuant to the product of nature doctrine. The conceptual foundation of the proposed framework is derived from a harmonization of the statute with patent jurisprudence. Part IV then applies the new framework to traditional inventions and emerging technologies.

I. STATUTORY DEVELOPMENT OF PATENT-ELIGIBLE SUBJECT MATTER

An examination into the constitutional basis and historical development of the patent statute reveals the legal contours that outline the foundation for the framework proposed in this Article. The Intellectual Property Clause of the U.S. Constitution grants Congress the authority to enact patent laws that “promote the Progress of Science and useful Arts.”¹⁹ Rewarding inventors for their discoveries is a secondary purpose, and merely a means to achieve this stated end.²⁰

¹⁷ Decision trees are frequently utilized by the Patent Office as analytical frameworks for patent examiners. For example, following recent clarifications of subject matter eligibility, the Patent Office provided its examiners with decision trees to assist in making subject matter determinations. See Overview of Examination Instructions for Subject Matter Eligibility (August 2009), available at http://www.uspto.gov/patents/law/exam/101_interim_training.pdf

¹⁸ See Appendix A for a summary.

¹⁹ U.S. Constitution, Art. I, § 8, cl. 8.

²⁰ See, e.g., *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327 (1945); *United States v. Masonite Corp.*, 316 U.S. 265 (1942).

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As the Supreme Court has often remarked, this constitutional provision reflects a balance between encouraging innovation and stifling competition.²¹ The compromise not only requires patent monopolies to be limited in duration and scope, it mandates that patents shall not remove knowledge from the public domain or restrict free access to knowledge already available to the public.²² Accordingly, the structure of the laws governing patent-eligible subject matter, along with administrative application and judicial interpretation of the laws, must appropriately harmonize these policy objectives.²³

In his address to Congress in 1790, President Washington stressed the need to enact patent laws that promote advancements in “agriculture, commerce and manufactures”, three industries that, at the time, formed the backbone of the U.S. economy.²⁴ That same year, Congress passed the Patent Act of 1790, which defined eligible subject matter as “any useful art, manufacture, engine, machine or device.”²⁵ Through the Patent Act of 1793, Congress slightly modified the provision to include “any new and useful art, machine, manufacture or composition of matter, or any new or useful improvement thereof.”²⁶ Though Congress identified four broad categories of eligible subject matter,²⁷ it did not define the categories, thus leaving the scope of each category to be determined by the courts.²⁸

The word “art”, as used in the 1793 Act, is incorporated into the word “process” as defined in the current statute.²⁹ It was not until 1952 that the

²¹ See, e.g., *Bonito Boats Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 144 (1989); *Graham v. John Deere*, 383 U.S. 1, 6 (1966). See also *Deepsouth Packing*, 406 U.S. at 530 (highlighting “this Nation’s historical antipathy to monopoly”).

²² See *Bonito Boats*, 489 U.S. at 144; *Graham*, 383 U.S. at 6; *Bilski*, 130 S. Ct. at 3227 (tests for patent-eligible subject matter must be mindful not to obscure “the larger object of securing patents for valuable inventions without transgressing the public domain”). See also *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 530-531 (1972) (in granting patent protection, “the rights and welfare of the community must be fairly dealt with and effectively guarded”) (citing *Kendall v. Windsor*, 62 U.S. 322 (1859)).

²³ See *Graham*, 383 U.S. at 6 (citing *McClurg v. Kingsland*, 42 U.S. 202, 206 (1843); *Gibbons v. Ogden*, 22 U.S. 1 (1824)).

²⁴ *Annals of Congress*, 1st Cong., 2d Sess., I, 932-933.

²⁵ Patent Act of 1790, 1 Stat. 109 § 1 (1790).

²⁶ Patent Act of 1793, 1 Stat. 318-323 (1793); *Bilski*, 130 S. Ct. at 3242-3243 (Stevens, concurring in judgment).

²⁷ As the Court notes, “in this country, the statute is as broad as language can make it.” *O’Reilly v. Morse*, 56 U.S. 62, 131 (1853).

²⁸ See generally Stephen Breyer, *On the Uses of Legislative History in Interpreting Statutes*, 65 S. CAL. L. REV. 845 (1992).

²⁹ *Diamond v. Diehr*, 450 U.S. 175, 182 (1981). As the Supreme Court has explained, a “process...is included under the general term ‘useful art.’” *Corning v. Burden*, 56 U.S. 252, 267 (1853).

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word “art” was replaced with word “process” in the patent statute.³⁰ Today, Section 101 of the Patent Act encompasses “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”³¹ Despite the change in language, the scope of subject matter encompassed by the four categories has remained constant.³² Interpretation of this statutory provision, however, has followed a drastically different course.³³

Coupled with the statutory categories outlined in Section 101, it is important to note the historical development of the method by which patent validity is determined. Under the 1793 Act, the Department of State was assigned the administrative role of maintaining a patent registry, while the courts were left to determine patent validity.³⁴ This system not only proved to be inefficient, it was found to encourage the filing of duplicative or fraudulent patents.³⁵ It was not until 1836 that Congress created the U.S. Patent Office, which was given the responsibility of examining the validity of patent applications.³⁶ Courts, however, retained the ability to review the validity of patents issued by the Patent Office.³⁷ Thereafter, in response to frequent problems related to the failure of inventors to precisely limit the scope of patent claims so as only to encompass subject matter eligible for patent protection, Congress amended the patent statute to include, among other provisions, a requirement that inventors define their property interest in a distinctly drafted claim.³⁸

³⁰ *Diehr*, 450 U.S. at 182. Although the 1952 Act defined the term “process”, the remaining three categories were left undefined. *Id.*

³¹ 35 U.S.C. § 101. Notably, the patent statute was amended, revised or codified approximately fifty times between 1790 and 1950. See *Bilski*, 130 S. Ct. at 3245.

³² *In re Nuijten*, 500 F.3d 1346, 1352 (Fed. Cir. 2007).

³³ For instance, in addition to the difficulty courts have encountered in excluding products of nature from patent-eligible subject matter, see *infra* Part II, the debate over the contours of what inventions properly fall under the process category continues to the present day. See, e.g., *Bilski*, 130 S. Ct. at 3242-3243 (Stevens, concurring in judgment). See generally, Robert A. McFarlane and Robert G. Litts, *Business Methods and Patentable Subject Matter Following In re Bilski: Is “Anything Under the Sun Made by Man” Really Patentable?*, *Santa Clara Computer & High Tech. L.J.* 35, 36 (2010).

³⁴ Patent Act of 1793, 1 Stat. 318-323 (1793).

³⁵ Dobyns, *THE PATENT OFFICE PONY: A HISTORY OF THE EARLY PATENT OFFICE* (1994), at 25.

³⁶ Patent Act of 1836, 5 Stat. 117 (1836).

³⁷ *Id.*

³⁸ Patent Act of 1870, 16 Stat. 198 (1870).

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Each of these Congressional acts sought to promote efficiency and fairness in the patent system, and create uniformity in application of the patent laws, all while furthering the public policy underlying the constitutional mandate. Despite repeated efforts to refine the patent statute to more accurately embody these principles, the statute remained noticeably silent in explaining a number of important issues.³⁹ Indeed, throughout the nineteenth century, patent litigation was rampant, and frequently culminated at the Supreme Court, where the Court not only painstakingly reviewed individual technologies for validity, but filled the statutory void through the establishment of several fundamental patent doctrines.⁴⁰

Included in this category of judicially created doctrines is the product of nature doctrine, which precludes from the realm of patentable subject matter those inventions that amount to a property interest over laws of nature, natural phenomenon, mental processes or abstract ideas.⁴¹ Although courts have frequently examined the product of nature doctrine as a bar to patent eligibility in individual cases, in the aggregate, the decisions provide ambiguous and conflicting precedent. I argue that, to a large extent, the ongoing debate surrounding which inventions qualify as patent-eligible subject matter stems from the failure of courts to accurately and adequately define the scope of the product of nature doctrine. The development and contours of the doctrine will now be examined.

II. THE JUDICIALLY-CREATED PRODUCT OF NATURE DOCTRINE

Despite broad statutory definitions and clear Congressional intent to establish a robust patent system, the laws governing patentable subject matter do contain limits and thus do not embrace every discovery.⁴² These limits, summarily referred to as “products of nature”, extend to laws of nature, natural phenomena, mental processes and abstract ideas.⁴³ Although not expressly codified in the patent statute, the product of nature doctrine is a longstanding

³⁹ Dobyms, *supra* note __, at 25.

⁴⁰ *Id.* These include nonobviousness, enablement and experimental use. *Id.* Notably, the Court issued over 500 patent-related opinions between 1852-1895. See *infra* note __.

⁴¹ *Benson*, 409 U.S. at 67.

⁴² *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). Courts have consistently noted that Congress intended the patent laws to encompass a broad range of inventions. For instance, the Framers clearly supported patent protection for subject matter that, historically speaking, was not protected in England. See *Curtis*, *supra* note __, at 19 (American patent law exhibits a “more liberal policy” than that of England).

⁴³ *Benson*, 409 U.S. at 67.

principle that courts and the Patent Office have applied to limit subject matter that is eligible for patent protection.

Notwithstanding frequent citation and reliance for patent invalidation, the concepts encompassed by the product of nature doctrine have not been clearly defined by the Supreme Court or Federal Circuit. Consequently, in the absence of any straightforward guidance, the Patent Office and district courts have been left to determine whether a particular invention is properly classified as a product of nature. Not surprisingly, inconsistent rulings have resulted. Furthermore, the presumption of validity that attaches to issued patents has been significantly discredited, which in turn jeopardizes both investments in emerging technologies and incentives to innovate.⁴⁴

Examining early opinions in product of nature jurisprudence informs contemporary discussion regarding the contours of the doctrine in relation to the patent statute. In particular, a judicious review of early decisions is important because it uncovers the theoretical foundation for excluding products of nature. This theoretical foundation is utilized to structure the parameters of the proposed framework.

As a review of the case law reveals, today's problems surrounding subject matter eligibility are modern-day versions of similar issues faced throughout the history of intellectual property protection.⁴⁵ With history as a guide,⁴⁶ the proposed framework represents an accurate harmonization of public policy with subject matter jurisprudence.

A. Early Developments in Product of Nature Jurisprudence

The genesis of the product of nature doctrine may be traced to a number of opinions dating to the mid-nineteenth century. These early cases reveal that the doctrine did not originate as a *per se* exclusion on subject matter eligible for patent protection. Rather, early cases excluded products of nature

⁴⁴ Approximately 40% of patents that are challenged in the courts have been found invalid. See *Molecular Pathology*, 2010 WL 1233416, at *35 (citations omitted). In addition, USPTO statistics indicate that 74% of issued patents challenged through reexamination proceedings were either canceled or amended. See *id.*

⁴⁵ Sherman, *THE MAKING OF MODERN INTELLECTUAL PROPERTY LAW* (Cambridge 1999) at 2.

⁴⁶ As Justice Holmes has noted “a page of history is worth a volume of logic.” *New York Trust Co. v. Eisner*, 256 U.S. 345, 349 (1921).

because they failed to meet a number of *other* statutory requirements, namely, those of novelty and disclosure.⁴⁷

Although patent jurisprudence has evolved to require that each statutory category be independently examined,⁴⁸ this obligation has never been expressly identified in the statute. As a review of the historical development of the product of nature doctrine reveals, however, maintaining a bright line between subject matter and the remaining requirements simplifies analysis of patent validity and serves to further the efficient allocation of resources within the Patent Office. For instance, a rejection on subject matter grounds would render unnecessary a number of costly and time-consuming processes such as prior art searches and analyses based on issues of novelty and non-obviousness.

This subpart focuses on two domains that are particularly relevant to elucidating the contours of the theoretical underpinnings of the product of nature doctrine: (i) the distinction between a natural principle and a process that applies a natural principle to some specific end and (ii) patent protection related to purified or isolated natural substances.

1. Distinguishing Principles from Processes

Supreme Court rumination on the product of nature doctrine dates back to the mid-1800s. In *LeRoy v. Tatham*, the Supreme Court discussed the validity of a patent for an improvement in machinery for making pipes and tubes where the novel component of the improved method was based on a newly discovered property of lead.⁴⁹ The Court distinguished the discovery of

⁴⁷ As used in this Article, the term disclosure encompasses the written description, best mode and enablement requirements. As the Federal Circuit has recently clarified, however, these are distinct legal requirements that each must be satisfied to constitute adequate disclosure under the terms of the statute. *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010).

⁴⁸ *Chakrabarty*, 447 U.S. at 309; *In re Bergy*, 596 F.2d 952, 960-961 (C.C.P.A. 1979). As Judge Rich notes, each of the statutory requirements is a hurdle that must be independently satisfied in order to receive patent protection. *In re Bergy*, 596 F.2d at 960-961 (indicating that the notion that the statutory requirements are “separate and distinct is long-standing and has been universally accepted”).

⁴⁹ 55 U.S. 156, 171-172 (1852). Although the validity of a jury instruction was at issue in *LeRoy*, *id.* at 177, the Court dedicated a significant portion of the opinion to discussing the scope of patentability available to processes that apply a newly discovered natural principle to some useful and practical end. *Id.* at 174-175. As the dissent highlights, the newly discovered natural quality of lead was believed, by those of ordinary skill in the art, to be impossible. *Id.* at 178 (Nelson, dissenting). Furthermore, the resulting pipes were less

the natural quality of lead from a specific application of the natural discovery.⁵⁰

As the Court noted, “it is admitted, that a principle is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.”⁵¹ In *LeRoy*, the Court reasoned that a patent on the newly discovered principle itself was improper because such a patent would serve to remove information from the public domain.⁵² Notwithstanding the unpatentability of the principle, the Court noted, a patent could issue for a *process* that utilized the newly discovered principle to some specific end.⁵³

Just one year after *LeRoy*, in *O’Reilly v. Morse*, the Supreme Court clarified the scope of patent protection available to a claim that applies a natural principle to a specific end.⁵⁴ The patent-at-issue in *Morse* centered on Samuel Morse’s telegraph, which applied the natural principle of electro-magnetism to creating a means for making intelligible marks at a distance.⁵⁵

expensive to make and were of superior quality, and thus proved to be quite a lucrative endeavor. *Id.*

⁵⁰ *Id.* at 174-175.

⁵¹ *Id.*; see also *Earle v. Sawyer*, 4 Mas. 6 (Story, J.) (“The thing to be patented is not a mere elementary principle, or intellectual discovery, but a principle put in practice and applied to some art, machine, manufacture, or composition of matter.”) (cited in Curtis, *supra* note ___, at note 1 § 6).

⁵² *LeRoy*, 55 U.S. at 175.

⁵³ *Id.* Interestingly, the dissent in *LeRoy* vigorously argued for extending the property interest to include, not only the method described by the applicants in their patent, but also to any pipe-manufacturing process that utilized the newly discovered natural principle. *Id.* at 188. According to the dissent, the “great feature” of the invention was not the particular apparatus, but the discovery of the natural principle that could be utilized in pipe manufacturing methods. *Id.* at 182. Such protection, the dissent noted, would not extend to the natural principle itself, such that others would be free to use the principle in methods other than pipe-manufacturing. *Id.* at 186-187. Although the majority properly limited the scope of patent protection to the precise method described in the patent, it briefly pondered whether the patent, if it were broadly written to cover any method of pipe-manufacturing that utilized this newly discovered natural principle, could be upheld. *Id.* at 177. In the end, however, the majority did not comment on this possibility, since the issue was not before the Court. *Id.* However, the *Morse* case, decided the following year, firmly addressed this precise issue, finding against patentability for a broadly written claim whose scope exceeds subject matter described in the patent specification. *Morse*, 56 U.S. at 119.

⁵⁴ 56 U.S. 62 (1853). In the first paragraph of the opinion, Chief Justice Taney highlights the importance of the case and the difficult questions that it raises. *Id.* at 106. In fact, the Court held off decision of the case, by extending it to the next term, for the purpose of additional deliberation. *Id.*

⁵⁵ *Morse*, 56 U.S. at 112.

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Although Morse invented one means of doing so, claim 8 of his patent was drafted to provide a property interest in *any* invention that utilized electro-magnetism to make intelligible marks at a distance.⁵⁶ According to the Court, such a broad claim was “not warranted by law.”⁵⁷

Morse supports the statement in *LeRoy* that a process claim that applies a natural principle to some specific end constitutes patent-eligible subject matter.⁵⁸ Under *Morse*, a claim constitutes patent-eligible subject matter so long as the scope of the claim is limited to the means described in the patent specification to produce the result or effect described in the patent, and nothing more.⁵⁹ The Court invalidated Morse’s claim 8 because the claim recited a property interest in abstract terms – namely, use of electro-magnetism to make intelligible marks at a distance – while the patent specification only identified one means of doing so.⁶⁰

Pursuant to this analysis, use of the word “abstract” is synonymous with the term “general.”⁶¹ Placed in other words, Morse’s claim sought to preempt *all* applications of electro-magnetism as it relates to creating intelligible marks at a distance, despite the fact that he only created one method of doing so.⁶² According to the Court, permitting such a claim would

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.* at 117-118. Justice Grier, in his dissenting opinion, elegantly summarizes this principle: “He who first discovers that an element or law of nature can be made operative for the production of some valuable result, some new art, or the improvement of some known art; who has 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.” *Id.* at 132 (Grier, dissenting). As Justice Grier further indicates, the “mere discovery of a new element, or law, or principle of nature, without any valuable application of it to the arts, is not the subject of a patent.” *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* at 120. The dissent highlights that this claim was characterized as a claim over “an abstraction”. *Id.* at 135 (Grier, dissenting).

⁶¹ *Id.* at 120 (indicating that Morse’s claim 8 amounts to a patent “for an effect produced by the use of electro-magnetism distinct from the process or machinery necessary to produce it”).

⁶² Indeed, under the reasoning set forth in *LeRoy*, had the patent specification described general uses of electro-magnetism for making intelligible marks at a distance, the claim would still be invalid for failing to identify *specific* applications of a natural principle. *LeRoy*, 55 U.S. at 175. The rationale underlying the *Morse* decision is analogous to Justice Story’s analysis in *Wyeth v. Stone*, 30 Fed. Cas. 723 (C.C.D. Mass. 1840). *Wyeth*, which was decided thirteen years prior to *Morse*, involved an invention for a new method of cutting ice. *Id.* at 725. Rather than claim ownership over the newly created method, the inventor claimed “an exclusive title to the art of cutting ice by means of any power, other than human power.” *Id.* at 727. According to Justice Story, such a claim is “utterly unmaintainable in point of law. It is a claim for an art or principle in the abstract, and not for any particular method or

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improperly reward Morse and deprive the public of a cognizable property interest to use electro-magnetism to make intelligible marks at a distance through methods other than those created by Morse.⁶³ For this reason, according to the Court, the claim failed to satisfy the disclosure requirement.⁶⁴

The rationale underlying the Court's analyses in *LeRoy* and *Morse* is summarized in a leading patent treatise, published by George Ticknor Curtis in 1854. Mr. Curtis takes an in-depth look at patent eligibility of inventions that implicate natural principles or abstract ideas. Upon a detailed examination of cases in both America and England, the treatise notes:

The consequences of allowing a patent for an abstract art or a principle, instead of allowing it only for a principle as applied to the production of a particular thing, or a particular result in matter, are apparent, when it is considered that principles are the elements of science; and if a patent could be taken for a newly discovered principle in science, it would cover every object to which that principle could be applied, and the whole field of the arts would thus at once be occupied by a few monopolists....The distinction is this: if a discovery consists merely in detecting some new property of matter, or of the elements of nature, or the laws of physics, but no special and positive application is made of it to specific fabrications, it is a discovery in science, or abstract mechanics, and not patentable; but if the discoverer makes use of such a new property, or avails himself of scientific or mechanical principles, for the production of a new substance, instrument or

machinery, by which ice is to be cut. No man can have a right to cut ice by all means or methods, or by all or any sort of apparatus, although he is not the inventor of any or all of such means, methods, or apparatus. A claim broader than the actual invention of the patentee is, for that very reason, upon the principles of the common law, utterly void, and the patent is a nullity." *Id.*

⁶³ *Morse*, 56 U.S. at 120-121 ("A different construction would be unjust to the public, as well as the patentee, and defeat the manifest object of the law, and produce the very evil against which it intended to guard."). Similar to the dissent in *LeRoy*, see *supra* note 50, the *Morse* dissent questioned the effect of disallowing a broad claim, reasoning that this would permit others to "pirate" the essence of that which Morse invented. *Id.* at 135 (Grier, dissenting).

⁶⁴ *Morse*, 56 U.S. at 118-119.

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machine, obtaining a result that is new, and of a vendible description, the particular mode of producing that particular thing may be the subject of a patent.⁶⁵

In this short excerpt from his masterful treatise, Mr. Curtis offers a succinct restatement of patent law that is consistent with analysis in the *LeRoy* and *Morse* opinions. Namely, subject matter eligibility may extend to a process that applies a natural principle to some specific end, but may never extend to a claim over the natural principle itself or to a claim that seeks ownership of an application that is not sufficiently described in the patent specification.

The foundation for this distinction may be traced to English common law in an 1844 decision by the Court of Exchequer in *Neilson v. Harford*.⁶⁶ In *Neilson*, the English court highlighted the fact that Neilson could not have a patent on a natural principle itself, even if he were the first to discover the principle, but that he was entitled to a patent for a process that applied the natural principle in some useful and novel way.⁶⁷ In analyzing the eligibility of the process, the *Neilson* court treated the natural principle itself as “being well known”.⁶⁸

In other words, *Neilson* characterizes natural principles as knowledge that has always existed in the public domain, despite entering the realm of human understanding at a particular time.⁶⁹ Pursuant to this analysis, natural principles may never satisfy the novelty requirement because they exist independent of man’s realization of their existence. This segment of the

⁶⁵ Curtis, *supra* note __, at 91-92. The treatise also addresses the role of a natural principle *vis-à-vis* a process that also recites a machine or apparatus. As Mr. Curtis indicates, the term “art” applies “to all those cases where the *application* of a principle is the most important part of the invention, and where the machinery, apparatus, or other means, by which the principle is applied, are incidental only and not of the essence of the invention.” *Id.* at 80. In such cases, although the machine or apparatus may not, in and of itself, be novel, novelty may lie in a *process* that utilizes a natural law, though use of an old machine or apparatus, to achieve a new end. In other words, novelty rests in the process that utilizes the newly discovered natural principle *and* applies the natural principle to some specific end. *Id.* at 12.

⁶⁶ 8 Meeson & Welsby 806 (1844). Neilson’s patent relates to method of interposing a receptacle for heated air between a blowing apparatus and a furnace. *Id.* at 823-824. Neilson directed the air to be heated in the receptacle, and then applied a blast to project the heated air into the furnace. *Id.*

⁶⁷ *Id.* at 823. Similar to the Supreme Court in *Morse*, see *supra* note 51, in the first sentence of the *Neilson* opinion, the English court highlighted the difficulty it faced in arriving at its decision. *Id.* at 822 (“We have, after much consideration, and not without some doubt and hesitation, arrived at the conclusion.”).

⁶⁸ *Id.* at 823.

⁶⁹ *Id.*; see also Curtis, *supra* note __, at 13-14.

Neilson case is extensively discussed in a number of early Supreme Court opinions,⁷⁰ thus suggesting that the high Court finds the distinction to be particularly relevant in determining whether an invention recites subject matter that is eligible for patent protection.

Likewise, the frequent citations suggest acquiescence to the proposition that natural principles may not receive patent protection because, under the terms of the patent statute, they can never be deemed new.⁷¹ In this respect, insofar as a natural principle itself is concerned, patent ineligibility is directly linked to the inability of such principles to be deemed novel, not to a determination that the principles may never be encompassed by the subject matter categories outlined in the patent statute. This may explain why the product of nature doctrine was not adopted as part of the patent statute or referred to in structuring the categories for eligible subject matter. Simply stated, whereas the novelty requirement seemingly captured all attempts to patent a natural product or principle, there was no practical need for (i) an independent doctrine or (ii) exceptions to the categories outlining patent-eligible subject matter. As will be discussed in more detail in this Article, there is a fundamental flaw in this reasoning that has contributed to the ambiguity surrounding the contours of patent-eligible subject matter.

The analysis in *Morse* was echoed in *The Telephone Cases*, where the Court closely examined Alexander Graham Bell's patent on the telephone.⁷² Bell utilized the natural principle of electricity for use in transmitting speech.⁷³ Similar to *Morse*, Bell sought patent protection over all methods of using electricity to transmit speech, despite the fact that he invented only one method of doing so.⁷⁴ The Court found this claim to be invalid, and limited the scope of the patent to the particular method that Bell outlined in the patent specification.⁷⁵ As the Court highlights: "It may be that electricity cannot be used at all for the transmission of speech except in the way Bell had discovered, and that therefore, practically, his patent gives him its exclusive

⁷⁰ See, e.g., *Morse*, 56 U.S. at 114-117; *Tilghman*, 102 U.S. at 723-725; *Risdon Iron*, 158 U.S. at 72-73. As Curtis notes, American "courts have, in truth, without using the same terms, applied the same tests of the sufficiency of invention, which the English authorities exhibit, in determining whether alleged inventions of various kinds possess the necessary elements of novelty." Curtis, *supra* note __, at 18.

⁷¹ See, e.g., *Morse*, 56 U.S. at 114-117; *Tilghman*, 102 U.S. at 723-725; *Risdon Iron*, 158 U.S. at 72-73.

⁷² 8 S. Ct. 778, 780 (1888).

⁷³ *Id.* at 782.

⁷⁴ *Id.*

⁷⁵ *Id.*

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use for that purpose; but that does not make his claim one for the use of electricity distinct from the particular process with which it is connected in the patent.”⁷⁶

Taken together, these early opinions dictate that a natural principle, in and of itself, is ineligible for patent protection because it may never be deemed to be new under the terms of the statute. In other words, the law presumes that these discoveries have always existed and, as a result, may not be deemed novel, despite entering the realm of human understanding at a particular time. Notwithstanding, a *process* that applies a natural principle to some *specific* end is eligible for consideration as patentable subject matter, so long as the process does not preempt all practical uses of the underlying natural principle and the patent claim is limited to the specific means created and described by the inventor. For such claims, the natural principle is simply treated as part of the prior art, and the entire process is evaluated pursuant to the statutory requirements of novelty, utility, disclosure and non-obviousness.

2. Purification or Isolation of Natural Substances

In addition to distinguishing between claims that seek ownership over a natural principle and claims that recite a process that applies a natural principle to some specific end, *LeRoy* comments on the scope of patent protection that may be awarded to purified or isolated natural substances. Specifically, the Court indicates that “processes used to extract, modify, and concentrate natural agencies” qualify as eligible subject matter, but that the “elements of the power” themselves do not.⁷⁷ As the Court states, the “elements of the power exist; the invention is not in discovering them, but in applying them to useful objects.”⁷⁸ In this respect, patent protection may extend to a process used to purify or isolate a natural substance or to a claim that applies the purified or isolated substance to a specific end, but not to the purified or isolated substance itself.

This distinction was reaffirmed in the 1874 case of *American Wood Paper Co. v. Fibre Disintegrating Co.* In *American Wood Paper*, the Court examined the patentability of a composition of matter that was extracted from a natural product and then purified.⁷⁹ In addition to the product claim, the

⁷⁶ *Id.*

⁷⁷ *LeRoy*, 55 U.S. at 175.

⁷⁸ *Id.*

⁷⁹ 90 U.S. 566 (1874). The substance at issue is a pulp, known as cellulose, that is suitable for the manufacture of paper. *Id.* at 594. This pulp had previously been obtained by

inventors received a second patent that claimed a process for isolating and purifying a natural product.⁸⁰ Following the reasoning of *LeRoy*, the Court denied patent protection for the product, highlighting the fact that the product was not substantially different from products that were already known.⁸¹ Importantly, the Court acknowledged that there was a slight difference in degree of purity when compared to previously known substances, but found this difference to be insufficient to warrant patent protection for claimed product.⁸² Although the Court upheld the process claims, the Court noted that the product of a new process does not automatically result in patentable subject matter.⁸³ Rather, the resulting product must be independently examined to determine if it is substantially different from any previously known substance.⁸⁴

Ten years after *American Wood Paper*, in *Cochrane v. Badische Anilin & Soda Fabrik*, the Court revisited the scope of patent protection for purified or isolated natural substances.⁸⁵ At issue was a patent on an artificial dye that was created by extracting a natural substance and combining the extract with additional substances.⁸⁶ In discussing the patentability of the artificial dye, the

others through various methods. *Id.* According to the Court, the two pulps were substantially similar substances and had similar purposes. *Id.*

⁸⁰ *Id.* at 593.

⁸¹ *Id.* at 593-596.

⁸² *Id.* at 596.

⁸³ *Id.* at 593-597.

⁸⁴ *Id.*

⁸⁵ 111 U.S. 293 (1884).

⁸⁶ *Id.* at 298-299. *Cochrane* was a complicated patent infringement case where both parties had competing patents on methods for creating artificial dyes. *Id.* at 308-311. Plaintiff's patent not only claimed a property interest in the artificial dye that he had created, but also in any artificial dye that was substantially similar to that which his process created, or one that was identified by the same name or chemical formula. *Id.* at 296-301. Although the products of both plaintiff and defendant were identified by their respective manufacturer as artificial alizarine, defendant's process proved to be the more efficient of the two for creating the substance. *Id.* Further, each product was purified with different substances. *Id.* at 310-311. Thus, although both were termed "artificial alizarine", each had a slightly different chemical formula. *Id.* In the end, since plaintiff failed to show that defendant used plaintiff's process to produce defendant's substance, or that defendant's substance could only be produced through plaintiff's process, infringement was not found. *Id.* at 310. Rather, the evidence presented at trial suggested that defendant's substance was created through defendant's process, and that his substance had a different chemical formula than that of plaintiff's substance. *Id.* at 310-311. Similar to *Morse* and *The Telephone Cases*, the patent-at-issue in *Cochrane* was overly broad, and thus failed to satisfy the disclosure requirement. *Id.* at 310-313. In construing the patent, the Court followed the reasoning of *LeRoy*, and limited the scope of the patent claim to the precise description outlined in the patent specification. *Id.* at 310-311.

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Court notes that the artificial dye had a chemical formula that was equivalent to the naturally occurring substance, and thus “was an old article.”⁸⁷ For this reason, the Court denied patent protection for the claimed product, but noted that a process for creating the product was patent eligible.⁸⁸

The reasoning applied by the Court in *LeRoy*, *American Wood Paper* and *Cochrane* was echoed by the Commissioner of Patents. In *Ex parte Latimer*, the Commissioner affirmed the rejection of a claim that sought patent protection for a newly discovered fiber portion of a particular pine needle.⁸⁹ Through extensive research, the applicant was able to isolate fiber from a pine needle, and sought patent protection for the process of isolating the fiber and the fiber itself.⁹⁰ Although the process was deemed to constitute eligible subject matter, the fiber itself was not.⁹¹ According to the Commissioner, the fiber itself was not created by the applicant’s process, nor did his isolating process alter the naturally-occurring fiber.⁹² Rather, the isolated fiber was merely that “which nature had produced and which nature had intended to be equally for the use of all men.”⁹³

Whereas the fiber created by the process was equivalent to other fibers, it was deemed to be “old”, thus implicating arguments raised by prior Court opinions regarding the lack of novelty in natural phenomenon.⁹⁴ Furthermore, according to the Commissioner, even if this were the first time that fiber was isolated from its natural environment, the fiber would still not be eligible for patent protection, since granting a patent on the fiber would amount to granting a property interest in a natural element, which would be “unreasonable and impossible” insofar as it would amount to improperly removing information from the public domain.⁹⁵

Highlighting the utility of the newly isolated fiber and the complicated process of isolation, the Commissioner nonetheless limited patent protection to the process of isolation, and not to the isolated product.⁹⁶ In doing so, the

⁸⁷ *Id.* at 311-312.

⁸⁸ *Id.* Similar to reasoning of *LeRoy* and *Neilson*, lack of novelty is the foundation for the *Cochrane* Court’s position that such a product does not constitute subject matter that is eligible for patent protection. *Id.*

⁸⁹ 1889 Comm’r Dec. 123, 127 (1889).

⁹⁰ *Id.* at 124-125.

⁹¹ *Id.* at 127.

⁹² *Id.*

⁹³ *Id.* at 125-126. In finding that the fiber did not warrant patent protection, the Commissioner highlighted the *American Wood Paper* and *Cochrane* decisions. *Id.* at 124.

⁹⁴ As, for instance, set forth in *Morse*, *Tilghman* and *Risdon Iron*. See *supra* notes ___ - ___ and accompanying text.

⁹⁵ *Id.* at 125-126.

⁹⁶ *Id.* at 126-127.

Commissioner noted that, had Mr. Latimer included a final step in his process, such as altering the isolated fiber or giving it some new quality, the altered fiber would be eligible for patent protection so long as it “became something new or different from what it is in its natural state.”⁹⁷ According to the Commissioner, for an isolated natural product to receive patent protection, any alteration to the product must not be the result of “forces of nature.”⁹⁸ Notwithstanding any such alteration, however, mere isolation of the fiber did not warrant patent protection for the isolated fiber itself, even assuming Mr. Latimer was the first to do so.⁹⁹ The Commissioner’s decision is relevant for many reasons, one of which is that it properly analyzes the patentability of the isolated product on an analysis of the substance itself, rather than the utility or novelty of the new product. For this reason, *Ex parte Latimer* is significant in that it properly distinguishes subject matter as a distinct statutory requirement.

As the aforementioned cases highlight, the Supreme Court had an active patent docket between 1852 and 1895. Indeed, one often overlooked fact is that, during this time period, the Court issued more than 500 patent-related opinions.¹⁰⁰ Lower court application of this precedent proved to be problematic, as evidenced by the drastically inconsistent rulings amongst the lower courts. Taken together, the challenges faced by lower courts may properly be linked to the fact-intensive inquiry required of individual inventions, the apparent and stated difficulty that courts faced in attempting to understand the invention-at-issue, and the lack of robust framework for determining patent-eligible subject matter.

For instance, in *Keuhmsted v. Farbenfabriken of Elberfeld Co.*, the Seventh Circuit held that two products with an identical chemical formula may, nonetheless, differ widely as to level of purity, and thus, one or both of the products may constitute eligible subject matter.¹⁰¹ In *Keuhmsted*, the court was presented with a form of aspirin that was therapeutically superior to previous forms.¹⁰² Although the new process altered the characteristics of

⁹⁷ *Id.*

⁹⁸ *Id.* at 126.

⁹⁹ *Id.* According to the Commissioner, such isolation was akin to a pebble that had broken off a larger rock found deep in the sea, that had found its way to a seashore via sea currents and waves. *Id.*

¹⁰⁰ This number is based on a review of opinions returned from a Westlaw search for patent-related cases during the aforementioned time period.

¹⁰¹ 179 F. 701, 703-705 (7th Cir. 1910).

¹⁰² *Id.* Aspirin contains salicylic acid, which has significant therapeutic benefit but also adversely affects the stomach. *Id.* at 704. Through use of a new chemical process, the resulting aspirin was able to maintain the salicylic acid in a bond for an extended period of

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aspirin, and thus arguably created a new product despite the fact that the new aspirin had the same chemical formula as other forms of aspirin, the Seventh Circuit indicates that it makes “no difference” that the medicine was “lifted out of a mass” that contained the chemical compound.¹⁰³

The court then states that, in instances where two products are based on natural substances and have an identical chemical formula, but are purified to some extent, patentability is warranted so long as the purified product contains some therapeutic benefit that was not previously available.¹⁰⁴ Pursuant to this analysis, and contrary to Supreme Court precedent, patentability is not linked to a *substantial* difference in the underlying substance, but rather to a difference in utility. In deciding subject matter eligibility for the aspirin, the *Keuhmsted* court fails to discuss the *American Wood Paper* standard, which requires the substances themselves to be *substantially* different.¹⁰⁵ Likewise, the court does not address the *Cochrane* standard, which found an artificial substance patent ineligible where the substance had a chemical formula that was identical to a previously known substance.¹⁰⁶ Clearly, for the *Keuhmsted* court, the underlying utility of the new aspirin took precedence.

Just one month after the decision in *Keuhmsted*, a similar analysis was applied by the Second Circuit in *Union Carbide Co. v. American Carbide Co.*¹⁰⁷ The patent in *Union Carbide* contained a single claim – that for a new form of crystalline calcium carbide.¹⁰⁸ Prior to the invention, calcium carbide existed only in an amorphous condition, due either to the method of its preparation or the impurities that it contained.¹⁰⁹ The new product was a purer version of calcium carbide, and was useful for conversion into other compounds.¹¹⁰

As with the Seventh Circuit in *Keuhmsted*, the Second Circuit in *Union Carbide* focused on the utility of the new product, and side-stepped the issues of novelty and subject matter eligibility.¹¹¹ Specifically, the court states: “To

time, such that the acid would remain bonded as the aspirin passed through the stomach, but then would be released when the acid reached the intestines. *Id.* This aspirin was thus therapeutically more effective and less likely to cause adverse side effects. *Id.*

¹⁰³ *Id.* at 705.

¹⁰⁴ *Id.*

¹⁰⁵ *American Wood Paper*, 90 U.S. at 593-596.

¹⁰⁶ *Cochrane*, 111 U.S. at 311-312.

¹⁰⁷ 181 F. 104, 105 (2d Cir. 1910).

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.* at 106-108. Rather, the court indicates that novelty can be found by focusing on “superior efficiency”, “superior durability”, “purity”, “comparative cheapness” or “commercial success”. *Id.* at 106-107.

hold an important discovery which has given to the world a commercially new product – a product the high utility of which must be conceded – not entitled to protection for want of novelty, would, as it seems to us, be applying the patent statute to defeat its fundamental purposes.”¹¹² Similar to the Seventh Circuit in *Keuhmsted*, the Second Circuit in *Union Carbide* did not cite or distinguish *LeRoy*, *American Wood Paper*, *Cochrane* or *Ex parte Latimer*.

The following year, in *Parke-Davis Co. v. H.K. Mulford Co.*, Judge Hand issued an opinion that followed the reasoning of *Keuhmsted* and *Union Carbide*.¹¹³ The patent-at-issue centered on a natural substance that was isolated from an animal gland, and then subjected to a purification process.¹¹⁴ Prior to the discovery, it was unclear whether one could successfully isolate the substance from the animal gland, and then use it therapeutically in humans.¹¹⁵

The Patent Office denied the original patent application, citing the *American Wood Paper* decision, because the claim recited a property interest in the isolated natural substance.¹¹⁶ In denying the claim, the Patent Office noted that any product that is not altered after isolation from its natural surroundings is not patentable.¹¹⁷ Thereafter, the applicant amended the claim to include a purification step.¹¹⁸ The revised claim, which was subsequently issued, provided a property interest in “any substance which possesses the physiological characteristics of the glands and is substantially pure.”¹¹⁹

Judge Hand upheld the validity of this claim.¹²⁰ He went a step further, however, and argued that even if the new product “were merely an extracted product without change, there is no rule that such products are not patentable.”¹²¹ Pursuant to Supreme Court precedent, however, this statement is clearly false.¹²² Notably, after making this claim, Judge Hand highlights the utility of the new product as a justification for patentability, and cites to the *Keuhmsted* and *Union Carbide* decisions.¹²³

¹¹² *Id.* at 108.

¹¹³ 189 F. 95 (C.C.S.D.N.Y. 1911) (hereinafter *Parke-Davis I*).

¹¹⁴ *Id.* at 97-102.

¹¹⁵ *Id.* at 103.

¹¹⁶ *Id.* at 101.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 101-102.

¹¹⁹ *Id.*

¹²⁰ *Id.* at 99-103.

¹²¹ *Id.* at 103.

¹²² See, e.g., *LeRoy*, 55 U.S. at 175; *American Wood Paper*, 90 U.S. at 593; *Cochrane*, 111 U.S. at 311-312.

¹²³ *Parke-Davis I*, 189 F. at 103.

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According to Judge Hand, given the significance of the scientific discovery, the inventor “should be entitled to a lenient construction, for he has been author of a valuable invention and has succeeded where the most expert had failed.”¹²⁴ Remarkably, in the paragraph that follows this statement, Judge Hand admits that he is “a man without any knowledge of even the rudiments of chemistry.”¹²⁵ Judge Hand then calls for change in the judicial system of the United States to a model akin to the German system, whereby judges with technical backgrounds and training rule on technical issues, lest American courts “continue to blunder along without the aid of unpartisan and authoritative scientific assistance in the administration of justice.”¹²⁶ On appeal, the Second Circuit narrowed the claim construction to include only the substance that was produced as a result of the method of isolation and purification that was described in the patent specification.¹²⁷ Judge Hand allowed patent protection over all substances that possessed the same characteristics as the substance produced by the method outlined in the patent, irrespective of the actual method used to create the substance.¹²⁸

Overall, early opinions that examined purified or isolated natural substances – namely, *LeRoy*, *American Wood Paper*, *Cochrane* and *Ex parte Latimer* – held that a purified or isolated substance itself is ineligible for patent protection, but that a process of purification or isolation may constitute eligible subject matter. The sole exception to this rule is where, after a substance is purified or isolated, an additional step is taken by man to alter the underlying substance so that the new substance is substantially different from any known substance. Pursuant to the aforementioned decisions, the fact that the substance does not exist in nature in an isolated or purified form is immaterial.

Notwithstanding these parameters, a string of lower court decisions from 1910–1918 turned the tide of subject matter eligibility with respect to purified and isolated natural substances. Notably, on a worldwide scale, this period was a time of disease, war and civil unrest, and at least one opinion directly speaks to the utility of the underlying invention *vis-à-vis* World War

¹²⁴ *Id.* at 115. Highlighting the significance of the discovery, Judge Hand argues that “all this *ought* to count greatly for the validity of the patent”. *Id.* (emphasis added). Judge Hand cites no precedent for his position.

¹²⁵ *Id.* Nearly 100 years later, this sentiment was echoed by Judge Sweet in the Myriad gene patent case. *Molecular Pathology*, 2010 WL 1233416, at *39 n.46.

¹²⁶ *Parke-Davis I*, 189 F. at 115.

¹²⁷ *Parke-Davis Co. v. H. K. Mulford Co.*, 196 F. 496, 497-498 (2d Cir. 1912) (hereinafter *Parke-Davis II*).

¹²⁸ *Id.*

I.¹²⁹ After the war, interpretation of patent doctrine became less uniform, with some courts returning to analyses analogous to those found in the *LeRoy*, *American Wood Paper*, *Cochrane* and *Ex parte Latimer* decisions.

For instance, in *General Electric Co. v. De Forest Radio Co.*, the Third Circuit examined process and product claims related to an isolated and purified form of tungsten.¹³⁰ The court begins by stating that patent protection for an isolated substance is warranted only where the substance is isolated from its natural environment and altered by man, to the extent that the alternation creates a substance that is substantially different from the non-altered isolated substance, and that the cause of the distinction between the substances is properly characterized as being the result of man's work.¹³¹ According to the Third Circuit, with respect to the patent-at-issue, although the purification process made the isolated tungsten stronger and more ductile, the court found that the difference between the substances was not substantial, and thus patent protection was unavailable.¹³²

The *General Electric* case is particularly noteworthy because of the fact that the court held that the claims were invalid despite the fact that tungsten did not exist in nature in its pure form. In particular, the court reasoned that, since tungsten is a naturally occurring element, all of its properties are natural by definition.¹³³ As the court noted: "What he produced by his process was natural tungsten in substantially pure form. What he discovered were natural qualities of pure tungsten. Manifestly, he did not create pure tungsten, nor did

¹²⁹ See, e.g., *Baker v. Kennedy Refractories Co.*, 253 F. 739, 742 (3d Cir. 1918). Historical analysis of patent law reveals that, at various periods, political sentiments regarding the importance of particular inventions or technology sectors often overshadow strict adherence to the language of the patent statute. Adelman, *supra* note __, at 13-14. The lack of uniformity was identified by the Supreme Court at least as far back as the mid-1800s. *LeRoy*, 55 U.S. at 181.

¹³⁰ 28 F.2d 641, 642-643 (3d Cir. 1928). See also *In re Merz*, 97 F.2d 599, 601 (C.C.P.A. 1935) (mere purification of a known material does not result in a patentable product unless the product has "properties and characteristics that were different in kind from those of the known product rather than in degree"); *J.E. Baker Co. v. Kennedy Refractories Co.*, 253 F. 739, 742 (3d Cir. 1918) (finding patent-eligible subject matter and highlighting the new physical and chemical characteristics of the purified product that render the purified product substantially different from the non-purified product or any other known product).

¹³¹ *Id.* at 642. On the other hand, had the applicant's process endowed the tungsten with characteristics different from those provided by nature, he would be entitled to a patent. *Id.*

¹³² *Id.* at 641-642. Thus, according to the court, since the claims sought ownership over the "natural qualities of pure tungsten", they could not be maintained. *Id.* at 642-643.

¹³³ *Id.*

he create its characteristics. These were created by nature.”¹³⁴ The court did, however, uphold the validity of several process claims related to isolation and purification of tungsten.¹³⁵ Interestingly, in arguing that both the process and product claims should be found valid, the dissent focused on the underlying utility of the product, and stressed the “daring and original step” taken by the inventor.¹³⁶

B. *Refining the Scope of the Product of Nature Doctrine*

Early Supreme Court opinions excluded products of nature from patent-eligible subject matter primarily through use of the novelty and disclosure requirements. Despite the intuitive appeal of using these requirements as a basis for precluding patent eligibility for products of nature, novelty and disclosure do not capture all concepts encompassed by the product of nature doctrine, and thus do not provide an adequate foundation for the establishment of a comprehensive framework for subject matter eligibility. This becomes particularly clear when claims that implicate mental steps and mathematical algorithms are at issue.

Whereas each statutory requirement furthers the public policy underlying the patent statute, the conceptual foundation for the novelty and disclosure requirements necessarily overlaps with the conceptual foundation for subject matter eligibility. Nevertheless, since each statutory requirement plays a different role in the overall patent framework,¹³⁷ courts must be mindful to distinguish the novelty of an invention, and whether a patent claim provides adequate disclosure, from whether an invention constitutes subject matter that the patent laws were created to protect.¹³⁸ As the Court has indicated, subject matter eligibility is a threshold requirement that must be addressed prior to discussing issues novelty, utility, non-obviousness and disclosure.¹³⁹

Although nineteenth century opinions highlight the theoretical basis for excluding certain subject matter under the product of nature doctrine, a number of more recent decisions enhance our understanding of the theory in relation to

¹³⁴ *Id.*

¹³⁵ *Id.* at 646-647.

¹³⁶ *Id.* at 649-650 (Buffington, C.J., dissenting in part). Compare *Merck v Chase Chemical Co.*, 273 F. Supp. 68, 80-84 (D.N.J. 1967) (focusing on utility of isolated and purified B-12 vitamin in finding the substance to constitute patentable subject matter).

¹³⁷ See, e.g., *In re Bergy*, 596 F.2d at 960-961.

¹³⁸ See, e.g., Conley and Makowski, *Rethinking the Product of Nature Doctrine*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 371, 397 (2003).

¹³⁹ See, e.g., *Diehr*, 450 U.S. at 188.

modern technologies. Not surprisingly, the lack of a consistent application of the product of nature doctrine carried into the twentieth century. In particular, the Supreme Court continued to blur the line as to how courts and the Patent Office should analyze inventions that implicate the product of nature doctrine in relation to the statutory requirements for patent protection.

Specifically, whereas early decisions frequently analyzed product of nature cases through the novelty, utility and disclosure requirements, more recent opinions have examined products of nature through the lens of non-obviousness. Three areas that I will explore in detail include living organisms, mathematical algorithms and computer software. The development of Section 101 jurisprudence in these areas is particularly relevant in analyzing current and emerging biotechnologies.

1. Product Claims and Living Organisms

Living organisms are not categorically excluded as patent-ineligible subject matter. Although the Patent Office has a long history of granting patent claims that provide a property interest in a living organism,¹⁴⁰ for purposes of this article, I will focus on two seminal Supreme Court cases: *Funk Brothers Seed v. Kalo Inoculant* and *Diamond v. Chakrabarty*.

In *Funk Brothers*, the Court examined a product claim covering a natural fertilizer for leguminous plants.¹⁴¹ The underlying invention was created by joining various species of *Rhizobium* bacteria.¹⁴² Although each *Rhizobium* species was known to protect certain types of legumes, no one species was applicable to all legumes.¹⁴³ Further, although others had attempted to combine various species into a mixed culture that could be applied to all legumes, previous combinations produced an inhibitive effect which in turn reduced the efficiency of the bacteria.¹⁴⁴ The inventor discovered that there were certain strains of the bacteria that did not exert an

¹⁴⁰ For instance, in 1873, the Patent Office granted Louis Pasteur a patent on a form of yeast, which is a living organism. See U.S. Patent No. 141,072. See also *Chakrabarty*, 447 U.S. at 314 n.9. Notably, the yeast was a purified form that was alleged to be “free from organic germs of disease. See U.S. Patent No. 141,072, claim 2. Pasteur was also granted a property interest in the method of producing the purified yeast. *Id.* at claim 1.

¹⁴¹ 333 U.S. 127 (1948).

¹⁴² *Id.* at 129-130.

¹⁴³ *Id.* As a result, farmers who grew several types of legumes were forced to buy separate inoculants (i.e., separate forms of the bacteria *Rhizobium*) for each crop. *Id.*

¹⁴⁴ *Id.*

inhibiting effect, and thus was able to create a mixed culture that could be used for all legumes.¹⁴⁵

In denying patent protection for the product claims, the Court noted that the inventor did not create the qualities of the bacteria, which include the state of inhibition or of non-inhibition, since the “qualities are the work of nature.”¹⁴⁶ For this reason, the Court argued, the bacteria itself “of course” was “not patentable”, since “patents cannot issue for the discovery of the phenomena of nature.”¹⁴⁷ The Court further stated:

The qualities of these bacteria, like the heat of the sun, electricity, and or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.¹⁴⁸

Herein lies a problem with the *Funk Brothers* decision. The Court correctly states that the application of a product of nature constitutes subject matter eligible for patent protection.¹⁴⁹ The Court then indicates that the product claims amount to such an application, but that once the natural principle (the non-inhibiting qualities of some strains of the bacteria) was discovered, the state-of-the-art made production of the aggregated bacteria a simple step.¹⁵⁰ As Justice Douglas states in the majority opinion, although the new product may have been the “product of skill, it certainly was not the product of invention.”¹⁵¹ Based on these statements, it appears the majority found the invention ineligible for patent protection on non-obviousness

¹⁴⁵ *Id.* at 130.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* Interestingly, the appellate court, similar to the *Keuhmsted*, *Union Carbide* and *Parke-Davis* opinions, focused on the utility of the new product and the fact that the combined fertilizer did not exist in nature. *Id.* at 130-131.

¹⁴⁸ *Id.* at 130.

¹⁴⁹ *Id.*

¹⁵⁰ *Id.* at 130-132.

¹⁵¹ *Id.* at 132.

grounds, not on statutory subject matter.¹⁵² A few sentences after this discussion, however, the Court leaves non-obviousness aside and wavers back into a discussion of eligible subject matter.¹⁵³

For these reasons, *Funk Brothers* provides somewhat ambiguous precedent. On the one hand, the Court affirms that the application of a law of nature does not *per se* violate the product of nature doctrine. Thereafter, the Court states that the invention-at-issue is an application of a newly discovered natural principle, but that it does not contain the requisite inventive leap, and thus is undeserving of patent protection. At another point in the opinion, however, the Court states that the product claims amount to a claim over the natural qualities of the bacteria, and thus are patent ineligible. Language regarding state-of-the-art and inventive leap is irrelevant to whether a claim recites subject matter eligible for patent protection. Rather, this discussion implies that an invention constitutes patent-eligible subject matter, but fails to satisfy the non-obviousness requirement. This inconsistency was highlighted by Justice Frankfurter in a concurring opinion.¹⁵⁴

More than thirty years after *Funk Brothers*, the Court revisited product claims that recite living organisms in the landmark decision of *Diamond v. Chakrabarty*.¹⁵⁵ Chakrabarty was issued a patent for a genetically engineered strain of bacteria that was used in cleaning oil spills.¹⁵⁶ Chakrabarty's bacteria could break down multiple components of crude oil in a way that no known

¹⁵² In fact, the district court found the product claims to be invalid for lack of inventive concept. *Id.* at 128.

¹⁵³ As the Court states: "There is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed. All that remains, therefore, are advantages of the mixed inoculants themselves. They are not enough." *Id.* at 132.

¹⁵⁴ In his concurring opinion, Justice Frankfurter recognizes the confusion in the majority's opinion. He states that Bond's invention does constitute eligible subject matter and is a new and useful invention. Justice Frankfurter lambasted the majority's discussion of the product of nature doctrine, arguing that everything may be deemed "the work of nature" and that "any patentable composite exemplifies in its properties 'the laws of nature.'" In this respect, Justice Frankfurter cautioned that the majority's opinion may lay the basis for denying patentability to a large area within existing patent legislation. *Id.* at 133-135. Justice Frankfurter concurred in the judgment, however, because he found the product claims to be insufficiently drafted in light of the disclosure requirement. *Id.* His analysis mirrors that of *Morse* and *The Telephone Cases*; namely, that patent protection was not warranted because the inventor sought a property interest over an abstract idea of combining certain strains of the bacteria, rather than limiting the patent to the specific combination that was discovered. *Id.*

¹⁵⁵ 447 U.S. 303 (1980).

¹⁵⁶ *Id.* at 305-306.

natural bacteria could.¹⁵⁷ Chakrabarty's created this new bacteria through a method of conjugation, a widely known selective cross-breeding process that involves an exchange of genetic material through a natural process analogous to sexual reproduction.¹⁵⁸

In a 5-4 decision, the Court upheld the validity of the product claims, indicating that a live, human-made microorganism may constitute patentable subject matter under Section 101.¹⁵⁹ Distinguishing the invention-at-issue from *Funk Brothers*, the Court highlighted that Chakrabarty produced a new form of bacteria "with *markedly different* characteristics from any found in nature."¹⁶⁰ As the Court stated: "His discovery is not nature's handiwork, but his own; accordingly, it is patentable subject matter under § 101."¹⁶¹

Focusing on the fact that Chakrabarty's bacteria was not known to have existed in nature, the Court emphasized that "a clear and logical distinction" exists between the discovery of a natural entity and the creation of a natural entity through a man-directed method of cultivation, where the new natural entity is not repeated in nature nor able to be reproduced by nature unaided by man.¹⁶² According to Court, the fact that the micro-organisms are alive is without legal significance for purposes of patent law.¹⁶³ In support of this statement, the Court highlights prior decisions emphasizing that "courts should not read into the patent laws limitations and conditions which the legislature has not expressed."¹⁶⁴ Congress has not distinguished subject matter based on "living and inanimate things", but rather has recognized a distinction between

¹⁵⁷ *Id.* at 309-311.

¹⁵⁸ U.S. Patent 4,259,444; Medical Microbiology (<http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=mmed&part=A468>) (indicating that conjugation has been utilized as a method of genetic engineering since the late 1940s).

¹⁵⁹ *Chakrabarty*, 447 U.S. at 309-310. The patent examiner had rejected the product claims for the bacteria on the grounds that (i) micro-organisms are products of nature and thus constitute patent-ineligible subject matter and (ii) living things are not patentable subject matter under Section 101 of the Patent Act. *Id.* at 306. The Patent Office Board of Appeals affirmed the second reason provided by the examiner, but rejected the first ground because Chakrabarty's bacteria does not occur in nature, but rather was created by Chakrabarty. *Id.*

¹⁶⁰ *Id.* at 309 (emphasis added).

¹⁶¹ *Id.* This reasoning parallels that of *Smith v. Snow* and *Waxham v. Snow*, companion cases where the underlying invention involved a method of hatching eggs that utilized natural principles. *Smith v. Snow*, 294 U.S. 1, 5-6 (1935). In the companion cases, the Court held that claimed method constituted patent-eligible subject matter because the inventor was about to "secure the performance of a function by a means which had never occurred in nature". *Waxham v. Smith*, 294 U.S. 20, 22 (1935).

¹⁶² *Id.* at 313 (citing Congressional testimony related to the Plant Patent Act of 1930).

¹⁶³ *Chakrabarty*, 447 U.S. at 313-314.

¹⁶⁴ *Id.* at 308.

“products of nature, whether living or not, and human-made inventions.”¹⁶⁵ According to the Court, Congress employed broad language in drafting § 101 because it intended to encompass unforeseeable inventions.¹⁶⁶

For purposes of this Article, the *Chakrabarty* decision is relevant for many reasons. To begin, the Court reaffirmed the validity of the product of nature doctrine. Moreover, the Court did not tie the doctrine to any other statutory requirement, as previous decisions, including *Funk Brothers*, had done. The implication is that, insofar as the product of nature doctrine is concerned, arguments as to non-obviousness, utility, novelty and disclosure are irrelevant to the determination of whether an invention constitutes patent-eligible subject matter.¹⁶⁷ Furthermore, in requiring the man-made organism to be markedly different from any known organism, the Court affirmed the statements in *American Wood Paper*, *Cochrane* and *Ex parte Latimer* that permit patent-eligible subject matter only where the new substance is substantially different from previously known substances.

Taken together, *Funk Brothers* and *Chakrabarty* highlight the irrelevance of a living/non-living distinction in arriving at a conclusion regarding subject matter eligibility for a particular invention. Rather, the appropriate inquiries are (i) whether a living organism is created by man, (ii) whether the new organism is substantially different from any known organism and (iii) where a living organism is not created by man, whether the organism is applied to some specific end. According to the Court, under these circumstances, the invention-at-issue may properly be deemed patent-eligible subject matter.

2. Mathematical Algorithms and Computer Software

The debate surrounding eligible subject matter and the product of nature doctrine was complicated by the advent of computer software technology and the increasing number of process claims implicating mathematical algorithms. The first such case to reach the Supreme Court was *Gottschalk v. Benson*, where the patent-at-issue claimed a process for converting binary-coded decimal numerals into pure binary numerals.¹⁶⁸ The claims were broadly written such that they did not specify use of the method to

¹⁶⁵ *Id.* at 313. See also *J.E.M. v. Pioneer*, 534 U.S. 124, 130 (2001).

¹⁶⁶ *Chakrabarty*, 447 U.S. at 315-316.

¹⁶⁷ See e.g., *Cooley*, *supra* note __, at 376.

¹⁶⁸ 409 U.S. 63, 64 (1972). The decision was unanimous, with Justices Stuart, Blackmun and Powell taking no part. *Id.* at 73.

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any technology, apparatus or end use.¹⁶⁹ Rather, the claims sought ownership over use of the method in a general-purpose digital computer.¹⁷⁰ The Court, synthesizing a number of previous cases dealing with eligible subject matter and the product of nature doctrine, explained:

While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be. That statement followed the longstanding rule that an idea of itself is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.¹⁷¹

The Court highlighted the broad language of the patent, and analogized the case to the nineteenth century cases of *Morse*, *Cochrane* and *The Telephone Cases*.¹⁷² Notably, the calculation in *Benson* could be conducted without the aid of a computer through a series of mental steps.¹⁷³ In addition to being “abstract”,¹⁷⁴ the algorithm had no “substantial practical application” apart from the uses claimed in the patent.¹⁷⁵ As such, the Court held that the patent amounted to a claim of ownership over an idea.¹⁷⁶ The Court further

¹⁶⁹ *Id.* at 64.

¹⁷⁰ *Id.* Two claims at issue were rejected by the Patent Office, but sustained by the Court of Customs and Patent Appeals. *Id.*

¹⁷¹ *Id.* at 67 (citing to *Mackay*, *Rubber-Tip Pencil* and *LeRoy*).

¹⁷² *Id.* at 68-69.

¹⁷³ The Court explains, citing to a book published in 1964 and titled “Understanding Digital Computers”, a digital computer “operates on data expressed in digits, solving a problem by doing arithmetic as a person would do it by head and hand.” *Id.* at 65. The “digits” refer to the binary system that is utilized by computer technologies, and the conversion of binary-coded decimal numbers could be accomplished mentally through a table. *Id.* (including reprint of table).

¹⁷⁴ *Id.* at 68.

¹⁷⁵ *Id.* Notably, the Court defined an algorithm as a “procedure for solving a given type of mathematical problem”. *Id.*

¹⁷⁶ *Id.* at 71-72. The Court states that it is “conceded that one may not patent an idea”, but that the “practical effect” of granting the patent would be to award a property interest over an idea. *Id.*

reasoned that the patent, as drafted, would “wholly pre-empt” the algorithm, and thus would amount to a patent over the mathematical concept that the algorithm expressed.¹⁷⁷ Accordingly, the patent did not constitute subject matter eligible for patent protection.¹⁷⁸

Following *Benson*, lower courts established a two-part test to determine patent eligibility for claims that recite a mathematical algorithm: (1) identify whether an algorithm is directly or indirectly claimed; and (2) if an algorithm is either directly or indirectly claimed, determine whether the claim would wholly preempt use of the algorithm.¹⁷⁹ If the claim would wholly preempt use of the algorithm, then the claim is interpreted to be a claim on the algorithm itself, and thus would be patent ineligible.¹⁸⁰ Under this test, a mathematical algorithm was defined as a “procedure for solving a given type of mathematical problem”.¹⁸¹ Importantly, no distinction was drawn between algorithms that express a scientific truth and algorithms that express a man-made method of addressing a given problem.

Six years after *Benson*, in *Parker v. Flook*, the Court addressed the validity of a patent on a method for updating alarm limits where an algorithm was the only novel feature of the process sought to be patented.¹⁸² In the first paragraph of the *Flook* opinion, the Court begins with the statement: “In *Benson* we held that the discovery of a novel and useful mathematical formula may not be patented.”¹⁸³ Despite argument as to the accurateness of this

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 71-73.

¹⁷⁹ *Diehr*, 450 U.S. at 203.

¹⁸⁰ *Id.*

¹⁸¹ *Benson*, 409 U.S. at 68.

¹⁸² 437 U.S. 584, 585 (1978). As the Court explains, during the process of catalytic conversion, conditions such as temperature, pressure and flow rates are constantly monitored. *Id.* If any of these variables exceeds a predetermined alarm limit, an alarm signals the presence of an abnormal condition. *Id.* Although these alarm limits are often fixed, during certain operations, the alarm limits must be updated to as to reflect optimal operating conditions and requirements. *Id.* The patent-at-issue covers any use of the inventor’s algorithm for updating the value of the alarm limit on any process variable involved in a process comprising catalytic chemical conversion of hydrocarbons. *Id.* Whereas there are a number of processes of that kind in the petrochemical and oil-refining industries, the claims cover a broad range of potential uses of the method. *Id.* However, as the Court notes, they do not cover every conceivable application of the formula. *Id.* at 585-586. Notably, in his petition for a writ of certiorari, the Acting Commissioner of the Patent Office feared that the ability to patent such claims would unduly burden the Patent Office, and alleged that patent protections for computer software would have a “debilitating effect” on the industry. *Id.* at 587-588.

¹⁸³ *Id.* at 585. *Flook* was a 6-3 opinion. *Id.* at 598.

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characterization,¹⁸⁴ the Court further indicates that the current case deals whether “the identification of a limited category of useful, though conventional, post-solution applications” of an algorithm qualifies a process as patent eligible subject matter.¹⁸⁵

In analyzing the claims, the Court states that the plain language of the statute does not directly address whether Flook’s method is patent eligible subject matter.¹⁸⁶ The Court, noting that the line between a patentable process and unpatentable principle is not always clear, highlights that “a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.”¹⁸⁷ Likewise, the Court states that the process as whole must be examined, and that the novelty of the algorithm “is not a determining factor at all.”¹⁸⁸ The Court then resurrects the *Neilson* opinion, and argues that, in determining whether the process constitutes patent-eligible subject matter, the algorithm must be treated as though it were part of the prior art.¹⁸⁹ At this point in the opinion, the Court sways from discussion of Section 101 to an analysis akin to a determination of whether the invention satisfies the non-obviousness requirement of Section 103.¹⁹⁰

¹⁸⁴ I posit that a more accurate summary of holding in *Benson* is that: (i) similar to *Morse* and *The Telephone Cases*, a claim is patent-ineligible subject matter where the claim does not properly limit use of a mathematical algorithm to some specific end, but rather claims use of an algorithm in general terms; and (ii) to the extent the claims in *Benson* equate to a property interest over a mental process, such that the calculation could be conducted by one of ordinary skill in the art without the aid of a computer or other calculating device, they are patent-ineligible. In addition to the subject matter objections, the patent failed to contain an adequate disclosure to support the reach of the claims, and thus did not satisfy the disclosure requirement.

¹⁸⁵ *Id.*

¹⁸⁶ *Id.* at 588.

¹⁸⁷ *Id.* at 589-590.

¹⁸⁸ *Id.* at 591-592.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.* at 593-594. Indeed, the patent-at-issue has a history of ambiguous analysis. Namely, the patent examiner rejected the application, indicating that the patent amounts to a “patent of the formula of mathematics itself” since the sole difference between the application and the prior art was the mathematical formula utilized in the claimed process. *Id.* at 587. The Board of Patent Appeals affirmed this rejection, relying on the point-of-novelty reasoning. *Id.* The Court of Customs and Patent Appeals reversed, finding that *Benson* only applied to claims that wholly pre-empt a mathematical algorithm, and that the applicant merely used a formula in conjunction with the remaining steps of the claim. *Id.* For the appellate court, since “mere solution of the algorithm” would not constitute patent infringement, the claim did not practically amount to a claim over the algorithm itself or wholly pre-empt use of the formula. *Id.*

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For instance, the Court states that “it is absolutely clear” that the application “contains no claim of patentable invention.”¹⁹¹ However, in detailing its reasons for holding as such, the Court points only to the lack of an inventive concept in the claimed process, not to a reason why the process fails to claim eligible subject matter.¹⁹² Furthermore, the Court does not mention how the disclosure requirement ties into the analysis, though it makes a point to highlight apparent deficiencies in this area.¹⁹³ Accordingly, it is unclear whether the inclusion of such additional factors would render a similar process patentable.

Given this ambiguity and lack of a coherent argument, the Court’s holding that the patent fails to satisfy § 101 is specious.¹⁹⁴ On the one hand, the Court acknowledges that an application of a product of nature is patent eligible.¹⁹⁵ On the other hand, the Court argues that this particular invention, although reciting an application of a product of nature, fails to qualify as eligible subject matter because the recited process does not contain any novel feature.¹⁹⁶ As Justice Stewart highlights in his dissenting opinion, these positions are directly at odds with one another.¹⁹⁷

¹⁹¹ *Id.* at 594

¹⁹² *Id.* As the Court explains, the claim “is unpatentable under § 101, 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.” *Id.* The Court then modifies the longstanding rule that the application of a law of nature to some specific end constitutes patent-eligible subject matter, see *infra* Part II.A.1, and argues that Section 101 is satisfied only where there is “an *inventive* application” of a natural principle or “some *inventive* concept” in the application of a natural principle. *Id.* (emphasis added). The Court does not cite to any precedent to support this position. *Id.*

¹⁹³ Specifically, the Court notes: The patent application does not purport to explain how to select the appropriate margin of safety, the weighting factor, or any of the other variables. Nor does it purport to contain any disclosure relating to the chemical processes at work, the monitoring of process variables, or the means of setting off an alarm or adjusting an alarm system. *Id.* at 586.

¹⁹⁴ In fact, at one point in the opinion, the Court indicates that the claimed process “provides a new and presumably better method for calculating alarm limit values.” *Id.* at 594-595.

¹⁹⁵ *Id.* at 591.

¹⁹⁶ *Id.* at 594-595.

¹⁹⁷ The dissent highlights this inconsistency in the reasoning of the majority. As Justice Stewart succinctly indicates in his dissenting opinion, the “issue here is whether a claimed process loses its status of subject-matter patentability simply because one step in the process would not be patentable subject matter if considered in isolation.” *Id.* at 599. This position runs contrary to well-settled patent law by “importing into its inquiry under 35 U.S.C. § 101 the criteria of novelty and inventiveness.” *Id.* at 600. For the dissent, the claims constitute patent-eligible subject matter for reasons similar to those provided by the appellate

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In the end, *Flook* established that the *Benson* rule was not limited, as the lower courts believed, to claims that wholly preempt a mathematical algorithm.¹⁹⁸ The Court then set forth a framework for determining whether a claim is patent eligible under Section 101: (1) the algorithm is treated as if it were a part of the prior art; and (2) the claim is examined to determine whether it discloses some other inventive concept.¹⁹⁹ In general, *Flook* was not enthusiastically received by the Court of Customs and Patent Appeals; the circuit court engaged in an extensive critique, and concluded that the Supreme Court erroneously commingled distinct statutory provisions that are conceptually unrelated.²⁰⁰

Three years after *Flook*, and just one year after *Chakrabarty*, the Court again took up the issue of whether a process that includes a mathematical formula constitutes eligible subject matter under Section 101. The case was *Diamond v. Diehr*, and the patent at issue involved a process for molding raw and uncured synthetic rubber into cured rubber.²⁰¹ The process contained several steps involving mathematical equations and programmed digital computers.²⁰² In a 5-4 decision, the majority found the patent eligible under Section 101.²⁰³

court. *Id.* at 599. Namely, the claims apply a mathematical algorithm to some specific end, do not preempt use of the algorithm and are not drafted such that solving the algorithm would amount to patent infringement. *Id.*

¹⁹⁸ *Diehr*, 450 U.S. at 204 (Stevens, dissenting).

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ 450 U.S. 175, 177 (1981).

²⁰² *Id.* at 177-179. The process utilizes heat and pressure in a mold, where the mold can accurately shape uncured synthetic rubber into a functional product. *Id.* at 177. To be useful, synthetic rubber must be cured at the proper temperature for a certain period of time. *Id.* Previous methods could not accurately calculate the temperature inside the mold, resulting in rubber that was not properly cured. *Id.* at 178. The applicants created a method that constantly measured the temperature inside the mold, and utilized a well-known cure-time mathematical equation to trigger a computer to alter the time that the rubber remained in the mold. *Id.* at 178-179.

²⁰³ *Id.* at 192-193. The patent examiner rejected the claims as constituting ineligible subject matter. *Id.* at 179-180. Citing to *Benson*, the examiner argued that, once the mathematical and computer steps were removed from the process, the process contained no inventive concept. *Id.* The Patent Office Board of Appeals affirmed the examiner's finding, but the Court of Customs and Patent Appeals reversed. *Id.* at 181. The circuit court argued that the process was patent-eligible subject matter because the claims were not directed to an algorithm *per se*, but rather were drafted to encompass a process for molding rubber that including, as just one step, use of a mathematical equation. *Id.* The Commissioner of the Patent Office sought certiorari, arguing that the circuit court's decision was inconsistent with Supreme Court precedent. *Id.*

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Citing to *Flook*, *Benson*, *Funk Brothers*, *Chakrabarty* and *LeRoy*, the majority opinion reaffirmed that products of nature are excluded from patent protection.²⁰⁴ The Court distinguished *Diehr* from *Flook* by indicating that, in *Flook*, the applicant simply sought to patent a mathematical formula for computing a number.²⁰⁵ On the other hand, the applicant in *Diehr* seeks to patent a process for curing rubber that utilizes a well-known formula, but does not seek to pre-empt the use of the equation.²⁰⁶ Rather, the applicant in *Diehr* sought to foreclose use of the equation in connection with the other steps of the claim.²⁰⁷ Such a process claim was in line with precedent that indicates that, at a threshold level, the application of a law or nature or mathematical formula constitutes patent-eligible subject matter.²⁰⁸ Whether a patent will ultimately issue depends on the ability of the claims to meet the remaining statutory requirements of novelty, utility, disclosure and non-obviousness.²⁰⁹

Diehr, however, goes a step further than merely reaffirming the long-standing rule that the application of a product of nature constitutes eligible subject matter. Rather, *Diehr* explains that, in determining whether a process claim constitutes patent eligible subject matter, it is improper to dissect the claim into components and evaluate the novelty of any one component.²¹⁰ In other words, the Court directly rejects the point-of-novelty approach.²¹¹ Under *Diehr*, all components of a process may fail the novelty requirement, yet the process itself may nevertheless constitute patent-eligible subject matter.

Coupled with these premises, the Court notes that when a claim recites a mathematical formula, an inquiry must be made into whether the claim seeks protection over the formula “in the abstract.”²¹² Citing to *Benson* and *Flook*, the Court explains that a mathematical formula, in and of itself, does not constitute eligible subject matter, and that limiting a formula to a particular technological environment or incorporating “insignificant post-solution activity” will not transform the patent claim in eligible subject matter.²¹³

²⁰⁴ *Id.* at 185. The Court also indicated that *Benson* and *Flook* “stand for no more than these long-established principles.” *Id.*

²⁰⁵ *Id.* at 186-187.

²⁰⁶ *Id.*

²⁰⁷ *Id.* at 187.

²⁰⁸ *Id.*

²⁰⁹ *Id.* at 191.

²¹⁰ *Id.* at 188-189.

²¹¹ As discussed, the point-of-novelty approach was applied in a number of cases, including *Neilson*, *Morse* and *Flook*. See, e.g., *id.* at 204.

²¹² *Id.* at 191.

²¹³ *Id.* at 191-192.

Rather, the process claim must be examined as a whole and, as the Court explained in *Morse*, where a claim recites application of a product of nature, the claim must be narrowly tailored to a specific end.²¹⁴

Overall, from 1972 to 1981, the Supreme Court addressed Section 101 in four separate opinions, three of which dealt with mathematical algorithms. As the decisions in *Benson*, *Flook* and *Diehr* demonstrate, applying the product of nature doctrine to process claims reciting mathematical algorithms proved to be a challenging endeavor. In particular, the Court repeatedly interwove extensive discussion of the novelty, non-obviousness, and disclosure requirements. This discussion only served to complicate the central issue of whether the invention qualifies as statutory subject matter. As the Court properly identified in *Chakrabarty*, whether an invention qualifies as patent-eligible subject matter is a distinct statutory requirement that must be resolved prior to discussion of the remaining statutory factors. Unfortunately, as a review of the case law reveals, courts have been unable to structure an appropriate framework for examining eligible subject matter that is consistent with this maxim. I posit that the proximate cause of this failure is the absence of a systematic and technology-agnostic method of analyzing whether an invention claims ownership over a product of nature.

²¹⁴ *Id.* Justice Stevens, writing for the dissent, argues that the majority reached the wrong decision because it misreads the patent-at-issue. *Id.* at 194. In arguing that the claims do not recite patent-eligible subject matter, Justice Stevens highlights failures in the patent disclosure. *Id.* at 205-206. In particular, he states that the patent application “teaches nothing about the chemistry of the synthetic rubber-curing process, nothing about the raw materials to be used in curing synthetic rubber, nothing about the equipment to be used in the process and nothing about the significance or effect of any process variable such as temperature, curing time, particular compositions of material, or mold configurations.” *Id.* Justice Stevens then argues that the Court’s effort to distinguish *Diehr* from *Flook*, through discussion of “insignificant post-solution activity” is misguided. *Id.* at 215. For Justice Stevens, the post-solution activity in both instances is significant. *Id.* However, this should not have any legal significance, because the post-solution activity “does not constitute a part of the inventive concept” of the patent. *Id.* (emphasis in the original). Justice Stevens argues for an analysis analogous to that set forth by the Patent Office, where certain components of the process claim are treated as part of the prior art and the claim is then analyzed to determine whether any inventive concept is revealed. *Id.* at 216. As discussed, however, this analysis improperly comingles the subject matter, novelty and non-obviousness requirements. See *infra* at ___. Justice Stevens concludes his dissenting opinion by proffering a new framework comprised of two steps: (i) a clear statement that “no program-related invention is a patentable process under Section 101 unless it makes a contribution to the art that is not dependent entirely on the utilization of a computer;” and (ii) “an unequivocal explanation that the term ‘algorithm’ as used in this case, as in *Benson* and *Flook*, is synonymous with the term ‘computer program.’” *Diehr*, 450 U.S. at 219-220.

III. CREATING A UNIFORM FRAMEWORK

The conceptual foundation for the framework proposed in this paper is based on a harmonization of the historical development of Section 101 and Supreme Court discussion of the categories of subject matter encompassed by the product of nature doctrine. At the outset, it is important to recall the purpose and function underlying the patent laws. The Intellectual Property Clause reflects a balance between encouraging innovation and stifling competition.²¹⁵ This compromise not only requires patent monopolies to be limited in duration and scope, it mandates that patents shall not remove knowledge from the public domain or restrict free access to knowledge already available to the public.²¹⁶ Accordingly, the patent laws not only define what may receive protection, but also identify what must remain accessible to the public.

Since 1793, Congress has chosen to keep constant the categories of subject matter that are eligible for patent protection.²¹⁷ This is significant, insofar as intense debate surrounding what subject matter should be eligible for patent protection has continued to the present day.²¹⁸ Moreover, despite ample opportunity to do so, Congress has not incorporated the product of nature doctrine into the patent statute, though the Congressional record reveals acquiescence to the principles of the doctrine.²¹⁹ As such, Supreme Court discussion of the doctrine provides the basis for how the doctrine should be interpreted in relation to the statute. Admittedly, much of the Court's discussion is dicta, and thus not controlling authority. Nevertheless, the discussion provides significant insight into the theoretical foundation for the product of nature doctrine, and thus is integral to an understanding of the principles underlying the doctrine and informative in structuring a practical framework for delineating ineligible subject matter.

Whereas patent law is not exempt from general rules of statutory interpretation, as with any issue of statutory construction, analysis must begin

²¹⁵ See, e.g., *Bonito Boats*, 489 U.S. at 144; *Graham*, 383 U.S. at 6.

²¹⁶ See *Bonito Boats*, 489 U.S. at 144; *Graham*, 383 U.S. at 6; *Bilski*, 130 S. Ct. at 3227.

²¹⁷ See, e.g., *Nuijten*, 500 F.3d at 1352; *Comiskey*, 499 F.3d at 1375.

²¹⁸ See generally *supra* notes 1-3.

²¹⁹ *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991) ("where a common law principle is well established...the courts may take it as given that Congress has legislated with an expectation that the principle will apply except where a statutory purpose to the contrary is evident").

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with the words of the statute.²²⁰ In interpreting the statute, one must examine both patent law precedent and non-patent statutory interpretation precedent.²²¹ As the Court has often remarked, words, unless otherwise defined, are interpreted by their ordinary and contemporary meaning.²²² Likewise, the judiciary “should not read into the patent laws limitations and conditions which the legislature has not expressed.”²²³

As a number of cases highlight, Congress has elected to use broad language to define categories of eligible subject matter.²²⁴ Specifically, Section 101 defines eligible subject matter as “*any* new and useful process, machine, manufacture or composition of matter.”²²⁵ The sole limitation to these four broad categories arises from the product of nature doctrine.²²⁶

Simply stated, a framework for defining eligible subject matter need only encompass and define the four categories outlined in the statute and the subject matter encompassed by the product of nature doctrine. Indeed, the recent *Bilski* opinion highlights this two-part analysis.²²⁷ The historical failure to arrive at an adequate framework for delineating eligible subject matter stems from the lack of clear definitions for these terms, as well as the juxtaposition of the additional statutory requirements into determinations of subject matter eligibility.²²⁸

²²⁰ See, e.g., *Chakrabarty*, 447 U.S. at 308; *Diehr*, 450 U.S. at 182. The meaning of a statute must, in the first instance, be sought in the language in which the act is framed. If that is plain, and the law is within the constitutional authority of the law-making body that passed it, the sole function of the courts is to enforce the law according to its own terms. *Caminetti v. United States*, 242 U.S. 470, 485 (1917).

²²¹ *Chakrabarty*, 447 U.S. at 308.

²²² *Id.*

²²³ *Id.*; *Diehr*, 450 U.S. at 182; *Bilski*, 130 S. Ct. at 3226.

²²⁴ See, e.g., *Chakrabarty*, 447 U.S. at 315-316; *Comiskey*, 499 F.3d at 1375. Whereas Congress performed its role by identifying eligible subject matter, in the absence of statutory definitions of the categories, the role of the judiciary is to construe the language employed by Congress. The courts must take the statutes as they find them, clarifying statutory language only where there exists an ambiguity. As the Supreme Court explains in *Chakrabarty*, Congress defined eligible subject matter in broad terms so as to further the constitutional mandate. As the Court notes, broad language “is not necessarily ambiguous when congressional objectives require broad terms.” *Chakrabarty*, 447 U.S. at 315-316. Indeed, broad language is preferable insofar as the emerging technologies are often unforeseeable. As the Court has noted, the inventions that bring the greatest benefit to mankind are frequently those that challenge the frontiers of science and industry. *Id.*

²²⁵ 35 U.S.C. § 101.

²²⁶ *Chakrabarty*, 447 U.S. at 309.

²²⁷ *Bilski*, 130 S. Ct. at 3225.

²²⁸ For instance, in describing the justification for the product of nature exceptions, the opinion of the Court in *Bilski* states that the exceptions are linked with the notion that an

As Justice Stevens explains, of central concern in determining subject matter eligibility for a particular invention is an understanding of what the applicant seeks to protect.²²⁹ Coupled with this determination, however, one must first have a clear understanding of the parameters of eligible and ineligible subject matter. Past opinions have failed to adequately and appropriately set these parameters because they have defined key terms in relation to a particular invention or technology sector,²³⁰ or have arrived at a determination of subject matter eligibility through intuition or analogy,²³¹ rather than taking a broader look at what factors are essential to something actually being deemed a product of nature.

I propose a new framework that is comprised of a series of conceptual questions that courts and the Patent Office should examine in order to determine whether an invention constitutes patent-ineligible subject matter. For each category of ineligible subject matter, the questions are structured so as to embody the principles underlying the product of nature doctrine, and may be applied to an invention in any industry or technology. The advantages of this methodological approach are highlighted through the application of the proposed framework to traditional inventions and emerging biotechnologies.

Though seemingly a straightforward process, one of the keys to establishing a workable framework is accurately capturing the concepts of the product of nature doctrine in technology-agnostic terms. Indeed, the difficulty in defining these concepts was identified by the *LeRoy* Court in 1852, a time far before any individual could imagine the myriad of technologies that would be introduced to society.²³²

Prior to discussing this method, I will begin with a definition of each of the four categories of statutory subject matter. If a claim does not recite subject matter encompassed by at least one statutory category, the claim must be denied as claiming ineligible subject matter.²³³ Also, it is important to keep

invention must be “new and useful”, see *id.*, rather than focusing on the fact that products of nature are not the type of subject matter that the patent laws were established to protect.

²²⁹ *Flook*, 437 U.S. at 593; *Diehr*, 450 U.S. at 194 (Stevens, dissenting).

²³⁰ See *Bilski*, 130 S. Ct. at 3227-3228 (highlighting limitations of technology-specific tests). See also Dan Burk and Mark Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L. J. 1155, 1156 (noting that patent law is technology-neutral in theory but technology-specific in application).

²³¹ See, e.g., *Chakrabarty*, 447 U.S. at 309-310 (describing product of nature doctrine by listing examples of patent-ineligible subject matter, rather than outlining factors to consider in determining whether an invention qualifies as a product of nature).

²³² *LeRoy*, 55 U.S. at 174.

²³³ See, e.g., *Nuijten*, 500 F.3d at 1352.

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in mind that this framework only applies to a determination of whether an invention qualifies as eligible subject matter. Whether a patent will ultimately issue largely depends on the ability of the patent to meet the statutory requirements of novelty, utility, disclosure and non-obviousness.²³⁴

A. *Defining the Statutory Categories*

Interestingly, the statutory category that has caused the most controversy is the sole category that is explicitly defined in the patent statute. Rather than head the statutory definition, courts have devised test after test with the purported goal of assisting courts, the Patent Office and the public in assessing whether an invention qualifies as a process under the terms of the patent statute. Despite the best efforts of the judiciary, these attempts have only served to further complicate the debate, and have failed to bring any clarity to the realm of patent-eligible subject matter. My goal in this subpart is to set forth definitions for the four statutory categories that are consistent with the constitutional mandate underling the patent laws. I have not created new definitions, but have selected definitions provided by courts that I think are properly derived in light of the statutory language, legislative history and doctrine of *stare decisis*.

PROCESS

The statute defines a process as a “process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”²³⁵ The Supreme Court has consistently utilized this definition when faced with an issue as to subject matter eligibility for processes.²³⁶ And, both the Supreme Court and the Federal Circuit have consistently interpreted

²³⁴ See, e.g., *Bilski*, 130 S. Ct. at 3225; *Comiskey*, 499 F.3d at 1371 (highlighting cases indicating that subject matter eligibility is a threshold matter that must be examined prior to issues of novelty, non-obviousness and other statutory requirements).

²³⁵ 35 U.S.C. § 100(b).

²³⁶ *Bilski*, 130 S. Ct. at 3225; *Diehr*, 450 U.S. at 181 n.6; *Flook*, 437 U.S. at 588 n.8; *Benson*, 409 U.S. at 64 n.2. The Federal Circuit in *Bilski*, on the other hand, characterizes the statutory definition as “unhelpful”, rather than acknowledging that Congress intentionally defined the word “process” in broad terms. *Bilski*, 545 F.3d at 951 n.3. Despite the Federal Circuit’s characterization in *Bilski*, statutory interpretation of the term process must be consistent with language of 100(b), which defines word process for the entire patent act. *Stenberg v. Carhart*, 530 U.S. 914, 941-942 (2000) (when statute includes an explicit definition, we must follow that definition, even if it varies from that term’s ordinary meaning).

the term process to require action.²³⁷ Accordingly, a process is properly defined as a series of acts or steps that must be carried out to produce a given result.²³⁸

Whereas the statute does not create a definitive test for determining whether an invention qualifies as a process, over the years, courts and commentators have attempted to fill this void through the creation of various tests.²³⁹ These tests include the “*Freeman-Walter-Abele*” test, “useful, concrete and tangible result” test, “machine-or-transformation” test and the “technological arts” test.²⁴⁰ Though each test provides insight into the contours of the process category, no single test has fully and accurately embodied the legislative intent and constitutional mandate.²⁴¹ Furthermore, each test has resulted in inconsistent results when applied across a diverse range of technologies.

Rather than focusing on process-specific tests, courts and the Patent Office should head the definition provided by Congress in Section 100(b), which defines the process category to include any process, art or method.²⁴² As noted, a process is defined as a series of acts or steps that must be carried out to produce a given result.²⁴³ The term art, though synonymous with the term process, is somewhat distinguishable from the terms process and method. As early cases indicate, the term art may properly be defined as “the employment of means to a desired end or the adaptation of powers in the natural world to the uses of life.”²⁴⁴ A method is defined as “an orderly procedure or process” or “regular way or manner of doing anything”.²⁴⁵

²³⁷ *Nuijten*, 500 F.3d at 1355.

²³⁸ *Id.*

²³⁹ See Duffy, *supra* note __, at 615.

²⁴⁰ *Id.*

²⁴¹ *Id.*

²⁴² The Federal Circuit in *Nuijten* succinctly and properly defines the process category as covering “an act or series of acts.” 500 F.3d at 1355.

²⁴³ *Nuijten*, 500 F.3d at 1355.

²⁴⁴ *Piper v. Brown*, 4 Fish, Pat. Cas. 175, Fed. Cas. No. 11,180. *Berardini v. Tocci*, 190 F. 329, 332 (C.C.S.D.N.Y. 1911). As the 1952 amendment indicate: “Art” as used in Section 101 has a different meaning than the words “useful arts” in the Constitution, and a different meaning than the use of the word “art” in other places in the statutes, and it is interpreted by the courts to be practically synonymous with process or method. The word “process” has been used to avoid the necessity of explanation that the word “art” as used in this place means “process or method,” and that it does not mean the same thing as the word “art” in other places. S. Rep. No. 82-1979, at 5 (1952), reprinted in 1952 USCCAN 2394, 2398.

²⁴⁵ *Bilski*, 130 S. Ct. at 3228.

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The statute does not limit the category to processes that involve technologies, or preclude processes that may be completed through a series of mental steps. Similarly, there is no requirement that the process meet the machine-or-transformation test, useful, concrete or tangible result test, or any other test.²⁴⁶ Furthermore, as cases during the industrial revolution held, the patentability of processes is not restricted to those involving chemical or other similar elemental action, but extends to a process or method involving mechanical operations.²⁴⁷

The inventions of yesterday's industrial revolution are akin to today's innovations in biotechnology and information technology. To the extent any eligibility test is created with a specific technology sector in mind, the test is likely to be limited in scope and applicability. In other words, the failure to adopt technology-agnostic definitions of concepts relevant to determining eligible subject matter has served to defeat the constitutional mandate that underlies the patent laws.

Along these lines, as a threshold matter, an invention is properly characterized as a process so long as it fits into the category of subject matter encompassed by the terms process, art or method. From a Section 101 perspective, the only remaining limitation will be if the process amounts to a property interest over a product of nature.

MACHINE

The common law defines a machine as "a concrete thing, consisting of parts, or of certain devices and combination of devices."²⁴⁸ This includes every mechanical device, or combination of mechanical powers and devices, that perform some function and produce a certain effect or result.²⁴⁹ One early decision highlights four classes of machines that qualify as patent-eligible subject matter: (a) where the invention embraces the entire machine, such as a railcar or sewing-machine; (b) where the invention embraces one or more elements of a category (a) machine, such as the divider of a reaping-machine; (c) where the invention relates to an improvement in an existing machine, and patent rights extend solely to the improvement; and (d) where all the elements of the machine are old, and where the invention consists in a new combination of those elements.²⁵⁰

²⁴⁶ See, e.g., *Bilski*, 130 S. Ct. at 3226.

²⁴⁷ *Expanded Metal Co. v. Bradford*, 214 U.S. 366, 386 (1909).

²⁴⁸ *Burr v. Duryee*, 68 U.S. 531, 570 (1863); *Nuijten*, 500 F.3d at 1355.

²⁴⁹ *Corning*, 56 U.S. at 267.

²⁵⁰ *Union Sugar Refinery v. Matthiesson*, 24 F. Cas. 686 (C.C. Mass. 1865).

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MANUFACTURE

Interestingly, since 1623, the term manufacture was the only word used to describe patentable subject matter under English law.²⁵¹ The term referred to both the process of manufacturing and the thing manufactured.²⁵² Under American patent law, the term evolved to include only the latter category. As early cases explain, the term manufacture applies to “anything made from raw materials by hand, by machinery, or by art”, that is not be classified as a design, machine or composition of matter.²⁵³ Today, the common law defines manufacture as an article produced from “raw or prepared materials by giving to these materials new forms, qualities, properties or combinations, whether by hand-labor or by machinery.”²⁵⁴ Such articles may be particular substances or commodities, but any such article must be tangible.²⁵⁵

COMPOSITION OF MATTER

A composition of matter includes any composition of two or more substances and all composite articles, whether they are the result of chemical union or of mechanical mixture.²⁵⁶ Compositions of matter include gases, fluids, powders or solids.²⁵⁷ Importantly, no distinction is drawn between living and non-living things.²⁵⁸

B. Delineating Products of Nature

The sole limitation on patent-eligible subject matter that is consistent with the legislative history and the historical development of patent jurisprudence, as well as the doctrine of *stare decisis*, is whether an invention

²⁵¹ Statute of Monopolies, 21 Jac. 1, c. 3 § 6 (allowing patents on “any manner of new Manufactures”).

²⁵² See 2 Samuel Johnson, A DICTIONARY OF THE ENGLISH LANGUAGE n90 (6th ed. 1785).

²⁵³ Riter-Conley Mfg. Co. v. Aiken, 203 F. 699, 701-703 (3d Cir. 1913).

²⁵⁴ *Chakrabarty*, 447 U.S. at 308; *American Fruit Growers*, 283 U.S. at 11; *Comiskey*, 499 F.3d at 1375 n.10.

²⁵⁵ *Nuijten*, 500 F.3d at 1351-1352. This requirement is analogous to the copyright laws, which require that eligible subject matter be fixed in a tangible medium of expression. See 17 U.S.C. 102.

²⁵⁶ *Comiskey*, 499 F.3d at 1375 n.10.

²⁵⁷ *Chakrabarty*, 447 U.S. at 308; *Comiskey*, 499 F.3d at 1375 n.10.

²⁵⁸ *Chakrabarty*, 447 U.S. at 308.

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amounts to a property interest over a product of nature.²⁵⁹ The proposed framework incorporates this limitation through a series of questions that courts and the Patent Office should employ in analyzing whether an invention seeks ownership over a product of nature.²⁶⁰ The framework utilizes questions, rather than descriptions or examples, in order to (i) avoid the historical failures of reasoning-by-analogy, (ii) remain applicable to emerging technologies and (iii) maintain a technology-agnostic approach to defining ineligible subject matter. The questions are structured so as to capture the integral characteristics of each product of nature category, while the theoretical justification for all categories lies in the notion that the patents must be limited in scope, may not remove information from the public domain and may not restrict free access to knowledge already available to the public.

Although the common law defines the product of nature doctrine as encompassing laws of nature, natural phenomenon, mental processes and abstract ideas, as will be discussed in this subpart, a more accurate categorization of subject matter encompassed by the product of nature doctrine includes natural principles, natural entities, mathematical algorithms, mental processes and abstract ideas. It is relevant to note that these categories, pursuant to the common law definition or that of the proposed framework, encompass inventions that are not, strictly speaking, products of nature. For example, mathematical algorithms are excluded from patent protection pursuant to the product of nature doctrine, despite the fact that such algorithms are often created by man.²⁶¹

As previously highlighted, at a fundamental level, to the extent an invention may be traced to some natural cause, it may be correctly be characterized as a product of nature.²⁶² Clearly, however, adopting such a materialistic approach would render the product of nature doctrine impractical.²⁶³ For this reason, across each product of nature category, in distinguishing events caused by nature from those caused by man, the principle of proximate cause is particularly helpful. In the proposed framework, the concept of proximate cause plays an integral role in determining whether a particular innovation is properly characterized as a product of nature or man.

1. Natural Principles

²⁵⁹ *Bilski*, 130 S. Ct. at 3225.

²⁶⁰ A summary of the proposed framework is set forth in Appendix A.

²⁶¹ *See infra* III.B.3.

²⁶² *See generally supra* note 8.

²⁶³ *Id.*

I define natural principles to include both laws of nature and natural phenomenon.²⁶⁴ Although they are distinct concepts, I group them under one heading because the theoretical basis for excluding each from patentable subject matter is identical. Namely, whereas both laws of nature and natural phenomenon exist independent of man and thus are not the result of the handiwork of man, they do not constitute subject matter that is eligible for patent protection.

Laws of nature refer to empirical observations of physical behavior that describe an aspect of the universe.²⁶⁵ Examples include the laws of physics, Einstein's theory of relativity, Newton's laws of gravity, quantum mechanics and the laws of thermodynamics.²⁶⁶ Natural phenomenon include any state or process in the universe that occurs or exists independent of man's knowledge of its existence, or that arises without man's assistance.²⁶⁷ These include tornadoes, lightning, volcanic eruptions, earthquakes, lunar eclipses and the aurora borealis. Natural principles also include the natural properties that govern the existence of every living and non-living organism or substance.²⁶⁸ Though natural phenomenon comport with laws of nature, they are not themselves laws of nature, but rather individual manifestations of the principles upon which the universe is based.²⁶⁹ Further, although there is some overlap between the two categories,²⁷⁰ recognizing a distinction facilitates analysis of patent eligibility across this product of nature category.

As the common law makes clear, natural principles are *per se* ineligible for patent protection.²⁷¹ Historically, this *per se* exclusion was founded on the

²⁶⁴ Philosophers of science have long debated the contours of definitions for these terms. Although I recognize the importance of this debate, for purposes of this Article, I will define the terms and note that amendment to the definitions does not alter the structure of the proposed framework, but rather the wording of questions one and two in this subpart III.B.1.

²⁶⁵ Oxford Dictionary; Stanford Encyclopedia of Philosophy ("laws of nature"). See generally, Swartz book; Fred J. Dretske, *Laws of Nature*, 44 *Philosophy of Science* 248 (1977); Craig Dilworth, *Principles, Laws, Theories and the Metaphysics of Science*, 101 *Synthese* 223 (1994); Stephen Mumford, *Normative and Natural Laws*, 75 *Philosophy* 265 (2000).

²⁶⁶ See, e.g., *Funk Brothers*, 333 U.S. at 130.

²⁶⁷ See, e.g., Richard Gray, *Natural Phenomenon Terms*, 66 *Analysis* 141 (2006). See generally Dretski, Mumford and Dilworth *supra*.

²⁶⁸ See generally Dretski, Mumford and Dilworth *supra*.

²⁶⁹ See generally Dretski, Mumford and Dilworth *supra*.

²⁷⁰ For instance, natural properties also exist independent of man's knowledge of their existence and arise without man's assistance.

²⁷¹ See, e.g., *Chakrabarty*, 447 U.S. at 309.

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inability of natural principles to be deemed new.²⁷² More recent cases properly base the exclusion on the fact that natural principles do not constitute the type of subject matter that the patent laws were created to protect.²⁷³ Notwithstanding patent ineligibility for natural principles, to the extent a patent claim applies a natural principle to some specific end, the claim is eligible for patent consideration so long as the claim does not preempt all practical uses of the natural principle.²⁷⁴ If a patent claim preempts all practical uses of a natural principle, the claim constitutes ineligible subject matter because it is deemed to be equivalent to a claim over the natural principle itself.²⁷⁵

In determining whether a claim seeks ownership over a natural principle, the following initial questions should be addressed:

1. Does the claim recite subject matter that refers to an empirical observation of physical behavior that describes an aspect of the universe?
2. Does the claim recite subject matter that refers to any state or process in the universe that occurs or exists independent of man's knowledge of its existence, or that arises without man's assistance?

These questions seek to determine whether a claim directly recites a property interest in a natural principle. For instance, if subject matter refers to an empirical observation of physical behavior that describes an aspect of the universe, it provides ownership over a law of nature. Similarly, if a claim recites subject matter that refers to any state or process in the universe that occurs or exists independent of man's knowledge of its existence, or that arises without man's assistance, it provides a property interest over a natural phenomenon. Granting a patent claim in either situation would remove information from the public domain and restrict free access to knowledge already available to the public, which is directly at odds with the constitutional mandate underlying the patent laws.²⁷⁶

The common law makes clear that man's discovery of a natural principle, regardless of the cost or difficulty involved in unearthing the discovery, will not result in a cognizable property interest in the discovery itself.²⁷⁷ Likewise, the fact that man may hasten the occurrence of a natural principle does not transform the natural principle into a manmade one, though

²⁷² See, e.g., *Tilghman*, 102 U.S. at 724-725.

²⁷³ See, e.g., *Chakrabarty*, 447 U.S. at 309.

²⁷⁴ See, e.g., *Morse*, 56 U.S. at 119.

²⁷⁵ *Id.*

²⁷⁶ See *Bonito Boats*, 489 U.S. at 144; *Graham*, 383 U.S. at 6.

²⁷⁷ See, e.g., *LeRoy*, 55 U.S. at 174-175.

the process that man employs may constitute patent-eligible subject matter.²⁷⁸ Similarly, the process used to discover the natural principle may constitute patent eligible subject matter.²⁷⁹

For any claim that applies a natural principle to some end, the following questions should be addressed in analyzing whether the claim recites patent-eligible subject matter:

3. If a natural principle is encompassed as part of a patent claim, is the natural principle applied to some specific end?
4. Would a patent on such a claim grant a property interest that effectively extends to the natural principle itself, apart from the specific end identified in the claim?
5. Would a patent on such a claim grant a property interest that extends to any additional practical use of the natural principle?
6. Is the application of the natural principle that is claimed in the patent something that exists, or existed, prior to man's creation of the application?

Questions 3-5 seek to determine whether a patent claim that applies a natural principle to some end preempts all known practical uses of the principle, or seeks ownership over use of the principle beyond the specific innovation described by the applicant in the patent. As the Supreme Court has held, the application of a natural principle to some specific end constitutes eligible subject matter, so long as the patent claim limits ownership to the specific end created by the inventor and the specific end does not preempt all known practical uses of the natural principle itself.²⁸⁰ An interesting scenario arises where a natural principle is only capable of being applied to one specific end. In such cases, any process claim would necessarily preempt all practical applications of the natural principle. As a result, any process claims that incorporate such natural principles would be patent ineligible, since a patent grant would restrict use of, or access to, the underlying natural principle, thus affording a property interest in the natural principle itself.

Question 6 seeks to determine if the application itself is one that exists, or existed, in nature. For instance, assume in year X that a scientist, within the confines of a university laboratory, applies a newly discovered natural principle to some specific end, and that the process does not preempt all known uses of the natural principle. A patent is awarded to this process in year X+5. In year X+9, however, another scientist discovers that this process is in fact

²⁷⁸ See, e.g., *id.*; *Smith v. Snow*, 294 U.S. at 6.

²⁷⁹ See, e.g., *LeRoy*, 55 U.S. at 174-175.

²⁸⁰ See, e.g., *Morse*, 56 U.S. at 119.

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something that occurs in nature. Under this scenario, although the patent may have been properly granted in year X+5, once it was determined that the process occurs in nature, the patent must be invalidated for lack of subject matter eligibility because the process claim amounts to a property interest over a natural principle. As a second example, assume that in year X+9, a scientist discovers that the process is in fact something that *occurred* in nature over one billion years ago. In this scenario, the patent must also be invalidated for lack of subject matter eligibility because the claim seeks ownership over something that existed in the universe prior to entering the realm of human understanding.²⁸¹

Overall, with respect to natural principles, outside of question 3, if any question is answered in the affirmative, the patent claim must be denied as patent ineligible subject matter for claiming ownership over a natural principle.²⁸² As will be discussed in more detail throughout subpart III.B, the second group of questions identified herein is also relevant to a determination of whether a claim seeks ownership over other product of nature categories.

2. Natural Entities

Natural entities include any element, substance, organism, plant or animal. In other words, a natural entity is any living or non-living thing that exists in the universe and is not the result of man's creation.²⁸³ Courts have often grouped natural entities under the general category of natural phenomenon.²⁸⁴ Conceptually, however, a distinction should be highlighted between the entity itself and the natural properties that govern the existence of the entity.²⁸⁵

²⁸¹ See, e.g., *Waxham v. Smith*, 294 U.S. 20, 22 (1935) (permitting patent protection on a process that applied a natural principle to a specific end, where the process itself was one that had never occurred in nature).

²⁸² If question 3 is answered in the negative, the claim must be denied as reciting patent-ineligible subject matter. See Appendix A for a summary.

²⁸³ See generally James G. Miller, *Living Systems: The Organism*, 48 *The Quarterly Review of Biology* 92 (1973); Thomas King, *On Life as a Separate Entity*, 64 *The Scientific Monthly* 161, 162 (1947).

²⁸⁴ See, e.g., *Chakrabarty*, 447 U.S. at 309; *Funk Brothers*, 333 U.S. at 130.

²⁸⁵ For instance, the majority of plants cannot live without photosynthesis. See Thomas E. Furman and James M. Trappe, *Phylogeny and Ecology of Mycotrophic Achlorophyllous Angiosperms*, 46 *The Quarterly Review of Biology* 219, 220-221 (1971). Some plants that can live without photosynthesis include Indian pipe (*monotropa uniflora*) and the snow plant (*sarcodes sanguinea*). See *id.* Classifying both plants and photosynthesis as natural phenomenon fails to capture this distinction. See generally, Herbert Hochberg,

As with natural principles, the common law unambiguously dictates that natural entities themselves do not constitute patent-eligible subject matter.²⁸⁶ Thus, should man discover a new plant, animal, element or organism, a patent over the natural entity itself is properly denied under Section 101 as encompassing ineligible subject matter.²⁸⁷ As earlier cases make clear, however, a more nuanced approach is required for purified or isolated natural substances.

The importance of the distinction between natural entities and natural principles becomes apparent as we examine patent protection for emerging biotechnologies. For instance, through germline gene therapy, a researcher may utilize a viral vector to insert a genetically modified allele into a host in an effort to replace a naturally occurring mutant allele.²⁸⁸ When successful, germline gene therapy replaces the naturally occurring mutant allele with the genetically modified allele.²⁸⁹ This genetically modified allele then alters the natural processes of the host, and may be transmitted to future generations.²⁹⁰ Does the fact that a human possesses a genetically modified allele alter that human's standing *qua* human? In other words, should this person now be deemed to be manmade? If so, what product or process claims are patent-eligible subject matter?

One possible characterization would state that the person is still a natural entity, but that one of the processes that governs the existence of that person is manmade. Another may be that the person is still a human, and the fact that a gene may have been altered is irrelevant in defining that person as a natural entity. A third would posit that, since the course of this person's natural evolution was altered by man, the person is properly deemed to be manmade. A fourth would state that, since that person does not exist in nature, and it is assumed could not occur in nature, the person is properly deemed to be manmade. In essence, the fundamental question is what does it mean to human? Although comprehensive discussion of this question is beyond the scope of this article, *Chakrabarty* provides significant guidance in arriving at an answer insofar as the patent laws are concerned.

Moore's Ontology and Non-Natural Properties, 15 *The Review of Metaphysics* 365 (1962) (discussing the distinction between natural qualities and natural objects).

²⁸⁶ *Chakrabarty*, 447 U.S. at 309.

²⁸⁷ *Id.*

²⁸⁸ See generally Stephen J. Russell, Gene Therapy, 315 *British Medical Journal* 1289 (1997).

²⁸⁹ See *id.*

²⁹⁰ See *id.*

Chakrabarty makes clear that a genetically modified living organism may constitute patent-eligible subject matter.²⁹¹ Recall that the basis for the Supreme Court's decision was that man created an organism that did not occur in nature and, it was assumed, did not exist in nature, and that the new organism was markedly different from any known organism.²⁹² Legislation passed after the *Chakrabarty* opinion purports to limit the scope of subject matter eligible for patent consideration, though there is some debate as to whether the legislation actually does so.²⁹³ Pursuant to the legislation, the sole limitation extends to claims that encompass human beings.²⁹⁴ This exclusion does not extend to any other species. In fact, patents have been issued for a wide range of genetically modified organisms, such as mice, rabbits and various plants.²⁹⁵

In order to properly conceptualize whether a patent claim seeks ownership over a natural entity, a variation of questions related to natural principles should be addressed. The first three Natural Entity questions, as with the first two Natural Principle questions, are essentially definitional.

1. Does the claim recite subject matter that refers to a living or non-living organism or substance that exists in the universe?
2. Is man the proximate cause of the existence of the living or non-living thing?
3. Does the claimed natural entity exhibit characteristics or contain properties that are substantially different from any known living or non-living organism or substance?

Similar to Natural Principle questions 1-2, Natural Entity questions 1-3 seek to exclude patent claims that directly recite a natural entity. As noted earlier, the concept of proximate cause is particularly helpful in determining whether nature or man is properly deemed to have created the natural entity.

An example provides additional guidance in understanding this concept. An apple is something that exists in nature, and thus may be deemed a natural entity. The fact that an apple turns brown once peeled refers to a natural phenomenon that apples undergo when placed in a specific environment. Apples turn brown when peeled because phenolic compounds in the fruit oxidize when a particular enzyme is exposed to oxygen.²⁹⁶ In its

²⁹¹ *Chakrabarty*, 447 U.S. at 314.

²⁹² *Chakrabarty*, 447 U.S. at 314.

²⁹³ For a detailed explanation, see *infra* IV.D.

²⁹⁴ See *id.*

²⁹⁵ See Gary Stix, *Owning the stuff of life*, *Scientific American* 76 (Feb. 2006). U.S. Patent 6,924,413.

²⁹⁶ See Nicolas, et al., *Enzymatic Browning Reactions in Apple and Apple Products*, 34 *Critical Reviews in Food Science and Nutrition* 109 (1994).

natural state, the apple's peel prevents the enzyme from coming into contact with oxygen.²⁹⁷ The oxidation of a peeled apple may be inhibited if the apple is placed in water, since the enzyme will not have access to oxygen; this, in turn, will prevent the browning.²⁹⁸ Notably, the same enzyme responsible for the browning – tyrosinase – is also found in humans.²⁹⁹ In humans, tyrosinase is important because it helps create melanin, which causes the skin to tan.³⁰⁰ A lack of tyrosinase in humans leads to albinism.³⁰¹

In this example, one may properly point out that a direct cause of the browning of a particular apple is the fact that a person decided to peel the apple. A more appropriate analysis indicates that, although true, the relevant distinction lies in the proximate cause of the browning, which is the natural reaction that a peeled apple undergoes when exposed to oxygen. The first person to peel an apple, though they may have been the first to observe the browning, has not created brown apples or the browning process. Rather, that person brought into human understanding a natural phenomenon of a natural entity. Moreover, the first person to isolate the enzyme as the reason for the browning did not create the enzyme or any property of the enzyme, but, again, simply brought an understanding of the enzyme, with respect to browning, into the realm of human knowledge. The danger of rewarding this person with a property interest over the enzyme, a property of the enzyme, or the process of browning are amplified once we realize that humans possess the same enzyme and that research into the process of creating melanin, through manipulation of the enzyme, may be a viable way of treating albinism.

As with natural principles, the common law extends subject matter eligibility to claims that apply a natural entity to some specific end.³⁰² For such claims, the following questions should be addressed:

4. If a natural entity is encompassed as part of a claim, is the natural entity applied to some specific end?
5. Would a patent on such a claim grant a property interest that effectively extends to the natural entity itself, apart from the specific end identified in the claim?

²⁹⁷ See *id.*

²⁹⁸ See *id.*

²⁹⁹ See William S. Oetting and Richard A. King, *Molecular Basis of Albinism*, 13 *Human Mutation* 99 (1999).

³⁰⁰ See *id.*

³⁰¹ See *id.*

³⁰² See, e.g., *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F. 453, 462-463 (2d Cir. 1908) (process claim that applied use of aerobes and anaerobes - two types of living organisms - to the treatment of sewage).

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6. Would a patent on such a claim grant a property interest that extends to any additional practical use of the natural entity?
7. Is the application of the natural entity that is claimed in the patent something that exists, or existed, prior to man's creation of the application?

The reasoning underlying the relevance of Natural Entity questions 4-7 mirrors that of Natural Principle questions 3-6. Namely, since the existence of all natural entities is not the result of the handiwork of man, natural entities do not constitute subject matter that is eligible for patent protection.³⁰³ However, to the extent a patent claim applies a natural entity to some specific end, the claim is patent eligible so long as the scope of the claim is limited to the specific use created by the applicant and the claim does not preempt all known practical uses of the natural entity.³⁰⁴ It is important to recognize that an analysis of purified or isolated natural entities requires additional clarification.

Since purified or isolated natural substances include two theoretically and practically distinct concepts, courts must be mindful to precisely identify the claimed subject matter in working through a subject matter analysis. Purification is a process that frees a natural substance of anything that debases, pollutes, adulterates or contaminates, or a process that removes foreign, extraneous or objectionable elements from a natural substance.³⁰⁵ Isolation is a process that separates or removes a natural substance from its naturally-occurring environment.³⁰⁶ A natural substance may be purified, isolated, or both purified and isolated. Furthermore, though both purification and isolation may alter the underlying natural substance itself, the extent of the alteration *and* the proximate cause of the alteration must be examined for proper analysis of subject matter eligibility pursuant to the product of nature doctrine.

The Supreme Court makes clear that, with respect to purified or isolated substances, "the processes used to extract, modify, and concentrate natural agencies, constitute the invention. The elements of the power exist; the invention is not in discovering them, but in applying them to useful objects."³⁰⁷ Accordingly, the following questions should be addressed in determining whether a purified or isolated substance constitutes patent eligible subject matter:

³⁰³ See, e.g., *Chakrabarty*, 447 U.S. at 309.

³⁰⁴ See, e.g., *Morse*, 56 U.S. at 119.

³⁰⁵ Oxford English Dictionary

³⁰⁶ Oxford English Dictionary

³⁰⁷ *LeRoy*, 55 U.S. at 174-175.

8. Does the purified or isolated substance exhibit characteristics or contain properties that are substantially different from the non-purified or non-isolated substance?
9. Is the proximate cause of any difference between the purified and non-purified substances the result of natural phenomenon that govern the properties of the substance when purified?
10. Is the proximate cause of any difference between the isolated and non-isolated substances the result of natural phenomenon that govern the properties of the substance when isolated?
11. Would a patent on the isolated or purified substance grant a property interest that extends to the non-isolated or non-purified substance?

In essence, Natural Entity questions 8-11 seek to determine whether a purified or isolated substance constitutes *subject matter* distinct from the non-purified or non-isolated substance, and whether the proximate cause of this new subject matter is the result of natural phenomenon that govern the properties of the substance when the substance is purified or isolated, or the result of the handiwork of man. As a review of the case law reveals, for the purified or isolated substance to be patent-eligible subject matter, man must intentionally alter the substance itself after purification or isolation, and the new substance must be substantially different from any known substance.³⁰⁸ Contrary to this position, a number of lower court decisions have justified patent eligibility simply on a new utility provided by the purified or isolated substances. As explained *infra*,³⁰⁹ these decisions are directly at odds with the Supreme Court's decisions in *LeRoy* and *Cochrane*.

As *LeRoy* and other cases explain, to the extent a claim seeks ownership over a process of purifying or isolating, the claim may qualify as patent-eligible subject matter.³¹⁰ In such instances, the following process-related questions should be addressed:

12. Would a patent on a process of purification or isolation grant a property interest that effectively extends to subject matter apart from the process created by the applicant?
13. Is the process of purification or isolation that is claimed in the patent something that exists, or existed, prior to man's creation of the process?

³⁰⁸ 1889 Comm'r Dec. at 125.

³⁰⁹ See *infra* II.A.2.

³¹⁰ *LeRoy*, 55 U.S. at 174-175.

For processes of purification and isolation, the primary concern is whether a patent on the process would grant a property interest to something other than the process created by the applicant. For example, the patent claim must be properly drafted so as to only encompass the process created by the applicant. Furthermore, in situations where there is only one method of purifying or isolating a particular substance, a property interest in the process would effectively extend to the purified or isolated substance. Accordingly, to the extent an example arises where there is only one method of isolation or purification, the process would constitute ineligible subject matter because of the downstream preemptive effect of the patent claim. And, as with any process claim, a patent on a process of purification or isolation is not proper where the process itself is something that exists or existed in nature.

3. Mathematical Algorithms

The Supreme Court defines a mathematical algorithm as a procedure for solving a given type of mathematical problem.³¹¹ Though this definition may be etymologically correct,³¹² exploring the various types of mathematical algorithms reveals a more accurate understanding of the appropriate level of subject matter eligibility for mathematical algorithms. In particular, a distinction must be drawn between algorithms that are mathematical expressions of natural principles, and mathematical algorithms that are created by man to address a particular problem.

Although a number of claims that recite mathematical algorithms have been declared to constitute patent-ineligible subject matter,³¹³ a close review of these cases reveals that patent ineligibility was arguably based on the fact that the underlying algorithm equated to a natural principle or mental process,³¹⁴ or that the claim failed to satisfy other statutory requirements such as non-

³¹¹ *Flook*, 437 U.S. at 585 n.1; *Benson*, 409 U.S. at 65.

³¹² An algorithm is properly defined as a specific set of instructions for carrying out a procedure or solving a problem. Mathematics is the systematic treatment of magnitude, relationships between figures and forms and relations between quantities that are symbolically expressed. As such, a mathematical algorithm may also be defined as a set of instructions for carrying out a procedure or solving a problem that utilizes symbolically expressed relationships between quantities, figures or forms through a systematic treatment of magnitude.

³¹³ See, e.g., *Flook*, 437 U.S. at 589; *Benson*, 409 U.S. at 67.

³¹⁴ See, e.g., *Diehr*, 450 U.S. at 187-188 (noting that equation itself was not patentable because the equation represents a law of nature); *Benson*, 409 U.S. at 65-67 (highlighting that the calculation called for by the algorithm could be performed “by head and hand.”)

obviousness or disclosure,³¹⁵ rather than a wholesale eligibility exclusion for mathematical algorithms. For instance, an argument can be made that, by definition, a mathematical algorithm qualifies as a process under Section 100(b) of the patent statute.³¹⁶ Indeed, neither the statute nor the legislative history dictate that mathematical algorithms constitute subject matter ineligible for patent protection. To the contrary, Section 100(b) of the patent statute may be read to expressly classify *all* algorithms as subject matter eligible for patent protection.³¹⁷ As with any other patent eligible process, the only limitation would be if the algorithm violates the product of nature doctrine.

This argument notwithstanding, the common law makes clear that a process is not unpatentable subject matter simply because it contains a mathematical algorithm.³¹⁸ Distinguishing between different types of mathematical algorithms, the Federal Circuit has noted that the common thread running through prior Supreme Court decisions regarding statutory subject matter is that mathematical algorithms that *express a natural principle or truth* are not the kind of discoveries that the patent laws were designed to protect.³¹⁹

Of course, a distinction must also be drawn between a patent on a mathematical algorithm itself from a patent on a process that applies a mathematical algorithm to some specific end. In the latter category, patent eligibility may be proper regardless of whether the algorithm at issue expresses a natural principle. Since a statutory invention may employ a scientific truth, a decision as to whether the invention utilizing such a truth is statutory must necessarily rest on the relationship which the truth or principle bears to the remainder of the substance of the invention claimed.³²⁰ As an early Supreme Court decision notes, patent eligible subject matter includes “structure created with the aid of knowledge of scientific truth.”³²¹

With these concepts as a backdrop, the proposed framework for determining whether a claim that recites a mathematical algorithm constitutes patent-eligible subject matter begins with the following question:

³¹⁵ See, e.g., *Flook*, 437 U.S. at 586-594 (noting deficiencies in disclosure and applying analysis that focuses on the lack of inventive concept in the claim).

³¹⁶ Insofar as a mathematical algorithm qualifies as a process, art or method, it is encompassed by the statutory definition of “process”.

³¹⁷ Insofar as an algorithm qualifies as a process, art or method, it is encompassed by the statutory definition of “process”.

³¹⁸ *Flook*, 437 U.S. at 590.

³¹⁹ *In re Walter*, 618 F.2d at 765.

³²⁰ *Id.*

³²¹ *Mackay Radio*, 306 U.S. at 94.

1. Does the mathematical algorithm express or represent a natural principle or natural entity?

If answered in the affirmative, the patent claim must be denied as constituting ineligible subject matter. However, in cases where a mathematical algorithm expresses a natural principle or entity and the patent claim applies the algorithm to some specific end, patent eligibility is satisfied so long as the patent claim does not extend to other uses not presented in the patent, preempt all known practical uses of the natural principle or entity as expressed in the algorithm, or represent an application that exists, or existed, prior to man's creation of the application. The following questions are useful in framing these concepts:

2. If a mathematical algorithm represents a natural principle or entity and is encompassed as part of a process, is the algorithm applied to some specific end?
3. Would a patent on the process grant a property interest that effectively extends to the natural principle or entity expressed in the algorithm, apart from the specific end identified in the patent claim?
4. Would a patent on the process grant a property interest that effectively extends to any additional practical use of the mathematical algorithm?
5. Is the application of the algorithm that is claimed in the patent something that exists, or existed, prior to man's creation of the application?

Conceptually, the rationale underlying Mathematical Algorithm questions 2-5 is identical to that of Natural Principle questions 3-6 and Natural Entity questions 4-7. Specifically, to the extent a patent claim encompasses a mathematical algorithm that expresses a natural principle or entity, and the claim applies the algorithm to some specific end, the claim constitutes patent-eligible subject matter so long as the claim is narrowly tailored to solely encompass the end identified in the claim and the claim does not preempt use of the natural principle or entity that is expressed by the algorithm.³²² Furthermore, such process claims may not equate to a process that exists, or existed, in nature prior to man's creation of the process.³²³

For claims in which a mathematical algorithm does not express or represent a natural principle or natural entity, but rather is series of steps created by man to solve a mathematical problem, two core concepts enter the calculus. The first is that patentable subject matter does not extend to claims

³²² See, e.g., *Morse*, 56 U.S. at 119.

³²³ See, e.g., *Waxham v. Smith*, 294 U.S. at 22.

that equate to mathematical equations.³²⁴ The second is that patent eligibility may extend to claims where a mathematical equation is a component of a claimed method.³²⁵ The classic example of such a claim is a business method patent that includes a mathematical equation as part of the claimed process.

In such claims, the mathematical algorithm represents a computation that assists a process relevant to some type of business or commerce. The variables of the algorithm are not necessarily representative of natural principles or entities, but rather are structured so as to produce a figure that then is utilized to produce a desired commercial result. Whether the patent claim, as a whole, amounts to a mental process or abstract idea is an additional factor that must be addressed in determining patentable subject matter.³²⁶ Prior to this analysis, however, the claim, as a whole, must be analyzed so as to reconcile the aforementioned concepts. Accordingly, the following questions should be addressed:

6. Does the patent claim apply a mathematical equation to some specific end?
7. Would granting the patent claim provide a property interest in a mathematical equation?
8. Would granting the patent claim provide a property interest in a mathematical equation apart from use of the equation in connection with the remaining steps of the claim?
9. Would granting the patent claim preclude any additional use of the mathematical equation?

In essence, these questions seek to unravel whether issuance of the patent claim would amount to a property interest over a mathematical equation, or would preempt the ability of others to use a mathematical equation in connection with steps that are not outlined in the method sought to be patented. Notably, in addition to the questions outlined in this subpart, the patentability of mental processes and abstract ideas plays an important role in determining whether patent eligibility extends to a claim that recites a mathematical equation.³²⁷

4. Mental Processes

³²⁴ *Diehr*, 450 U.S. at 191-192.

³²⁵ *Id.*

³²⁶ See *infra* III.B.4 and III.B.5.

³²⁷ See *infra* III.B.4 and III.B.5.

It is worthy to note that there may be some disagreement as to whether mental processes are encompassed by the product of nature doctrine. For instance, although the Supreme Court identifies mental processes as a product of nature category in *Benson* and *Flook*,³²⁸ other cases, such as *Funk Brothers*, *Chakrabarty*, *Diehr*, and *Bilski* do not include mental processes in the Court's definition of the doctrine.³²⁹ Moreover, in the late 1960s, the Federal Circuit repudiated the long-standing mental steps doctrine, which, for nearly four decades, was frequently utilized by the circuit courts, district courts and Patent Office to prevent the issuance of patent claims that included mental steps.³³⁰ Taken together, however, since the Supreme Court has identified mental processes as a product of nature category, and has never expressly excluded mental processes from the doctrine, it is proper to conceptualize the product of nature doctrine as encompassing mental processes.

All human activity involves mental processes,³³¹ some of which are conscious, the majority of which are unconscious.³³² Similarly, all innovations are the result of mental processes, and every patent application originates from mental processes.³³³ As the Federal Circuit has recently held, however, mental processes, standing alone, are not patentable, even if they have some practical application.³³⁴ This position follows the reasoning of the CCPA, which observed that "it is self evident that thought is not patentable."³³⁵ The primary

³²⁸ *Benson*, 409 U.S. at 67; *Flook*, 437 U.S. at 589. See also *LabCorp*, 548 U.S. at 126 (Breyer, dissenting from dismissal of writ).

³²⁹ Although Justice Kennedy's opinion of the Court does not include mental processes as a product of nature category, both concurring opinions do. *Bilski*, 130 S. Ct. at 3255, 3258.

³³⁰ *Diehr*, 450 U.S. at 195-196. A mental step was defined to include computations or "mental operations". *Id.*

³³¹ See, e.g., Eckhard Frick, *Self-Ascription, Awareness and the Unconscious*, 59 *Revista Portuguesa de Filosofia* 389 (2003).

³³² See *id.*

³³³ *Phillips v. City of Detroit*, 19 F. Cas. 509, 510 (C.C. Mich. 1879) ("Invention has been justly described as a mental process"); *Mergenthaler Linotype Co. v. International Typesetting Mach. Co.*, 229 F. 168, 175 (D.C.N.Y. 1914). See *Markman*, 517 U.S. at 386 (all patent claims are intellectual concepts expressed in language having physical embodiments).

³³⁴ *Comiskey*, 499 F.3d at 1377. See *In re Shao Wen Yuan*, 188 F.2d 377, 380 (C.C.P.A. 1951). "Purely mental steps are not patentable." *Abrams*, 188 F.2d at 169. Processes whose results can be apprehended only through the intellect are not patentable. *Shao Wen Yuan*, 188 F.2d at 381. It is considered well settled that processes involving mental operations and processes that merely produce a desired state of mind are not patentable. *Id.*

³³⁵ *Abrams*, 188 F.2d at 168. Support for this position may be traced back to English common law. "Nothing can be an object of property which has not a corporeal substance." *Millar v. Taylor* 98 ER 232 (1769) cited in *Sherman*, *supra* note ___, at 20. See also Kevin

reason for this exclusion centers on the fact that mental processes, along with natural principles and natural entities, are the basic tools of scientific and technological work.³³⁶

As noted throughout this article, the Supreme Court had identified exceptions to exclusions dictated by the product of nature doctrine. In *Flook*, the Court states that “a process is not unpatentable simply because it contains a *law of nature* or *mathematical algorithm*.”³³⁷ *Funk Brothers* indicates that, although products of nature are *per se* ineligible, eligible subject matter includes “the application of a *law of nature*” to some specific end.³³⁸ *Diehr* reaffirms the statements in *Flook* and *Funk Brothers*, indicating that “it is now commonplace that an application of a *law of nature* or *mathematical formula* to a known structure or process may well be deserving of patent protection.”³³⁹ In fact, this position echoes that from the 1939 *Mackay Radio* decision, which indicates that “while a *scientific truth*, or the *mathematical expression* of it, is not patentable invention, a novel and useful structure created with aid of knowledge of scientific truth may be.”³⁴⁰

Along these lines, *Diehr* further indicates that when a claim recites a “*mathematical formula, scientific principle* or *phenomenon of nature*,” an inquiry must be made into whether the claim is seeking patent protection for that thing in the abstract.³⁴¹ Based on these statements, it appears that the sole exceptions to the unpatentability of categories encompassed by the product of nature doctrine extend to patent claims that apply natural principles, natural entities or mathematical algorithms to some specific end. There is no Supreme Court opinion that includes use or application of a mental step as an exception to the doctrine.³⁴² This position is supported by a recent Federal Circuit opinion, which held that mental processes, standing alone, are not patentable, even if they have some practical application.³⁴³

The question still remains whether a patent claim that employs a mental step as a component of a patent claim constitutes eligible subject matter. In other words, does a process that incorporates both physical and mental steps

Collins, *Propertizing Thought*, 60 SMU L. REV. 317 (2007) (discussing appropriate limits for claims that recite mental processes).

³³⁶ *Benson*, 409 U.S. at 67.

³³⁷ *Flook*, 437 U.S. at 590.

³³⁸ *Funk Bros*, 333 U.S. at 127.

³³⁹ *Diehr*, 450 U.S. at 187.

³⁴⁰ *Mackay Radio*, 306 U.S. at 94.

³⁴¹ *Diehr*, 450 U.S. at 192.

³⁴² *Comiskey*, 499 F.3d at 1377.

³⁴³ *Id.*

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qualify as patent-eligible subject matter? Although the Supreme Court has not directly addressed this question,³⁴⁴ despite repeated calls to do so,³⁴⁵ an examination into leading decisions provides significant guidance. Whereas the common law supports the position that processes that employ purely mental steps are patent ineligible, there is no consensus amongst the lower courts as to subject matter eligibility for processes that employ both mental and physical steps. Some courts have looked past simply defining the steps of a particular process as either mental or physical, and have examined the role of the each step in the overall process.

Notably, this approach is consistent with the notion that a patent claim, as a whole, must be closely examined to uncover the precise nature of the property interest sought by the applicant.³⁴⁶ However, some courts have utilized this approach to examine the *novelty* or *non-obviousness* of the mental steps in analyzing subject matter eligibility.³⁴⁷ This approach comingles the requirements of Sections 102 and 103 with those of Section 101. The novelty of non-obviousness of a step of a process plays no role in the determination of whether the process recites patent-eligible subject matter. This “point-of-novelty” approach only serves to confuse statutory requirements, and is entirely improper when determining subject matter eligibility. Other courts have examined whether the overall patent claim *primarily* relies upon mental steps.³⁴⁸ In addition to being vague, this approach fails to examine the underlying *subject matter* of the claim itself.

To the contrary, an examination into the *type* of mental step being performed provides meaningful guidance in arriving at a determination of whether a particular patent claim recites patent eligible subject matter.³⁴⁹ Under the proposed framework, the mental step is examined to reveal the *subject matter* of the underlying mental process. To the extent a mental step involves solving a mathematical equation, the mental step may be analogized

³⁴⁴ See, e.g., *Shao Wen Yuan*, 188 F.2d at 381.

³⁴⁵ *Abrams*, 188 F.2d at 166; *LabCorp*, 548 U.S. at 126; *Prometheus*, 581 F.3d at 1336. See also Roger Klein and Maurice Mahoney, *Labcorp v. Metabolite Laboratories: The Supreme Court Listens, But Declines to Speak*, 36 J. Law, Medicine and Ethics 141 (2008).

³⁴⁶ *Bilski*, 554 F.3d at 958 (must examine patent claim as a whole).

³⁴⁷ *Musco Corp. v. Qualite, Inc.*, 1997 WL 16031, at *2 (Fed. Cir. 1997) (Where process is comprised solely of mental steps, at the very least, some aspect of these mental steps must be nonobvious, and the specification must enable one skilled in the art to practice the invention.). See also *Wheeling*, 413 F.2d at 1191; *Abrams*, 188 F.2d at 167.

³⁴⁸ See, e.g., *In re Hammack*, 427 F.2d 1384, 1259 (C.C.P.A. 1970).

³⁴⁹ The mere inclusion of mental steps in a patent claim does not invalidate the claim. *Musco Corp.*, 1997 WL 16031, at *2; *Alco Standard Corp. v. Tennessee Valley Authority*, 808 F.2d 1490, 1496 (Fed. Cir. 1986).

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to a mathematical algorithm. In such instances, the questions identified in subsection III.B.3 must be examined to determine if the mathematical algorithm (as expressed in a mental step of the claim) falls under an exception to the rule that such algorithms do not constitute patentable subject matter. On the other hand, if the mental step involves analysis of a situation or problem, apart from solving a mathematical equation, the entire process claim is properly deemed ineligible subject matter because, as discussed earlier in this subsection, the Supreme Court has not identified an exception to the unpatenability of mental processes. Accordingly, under the proposed framework, where a patent claim recites both mental and physical steps, each mental step must be examined to determine the underlying subject matter of mental step itself.

Whether the patent laws *should* permit patent claims that incorporate mental steps must be distinguished from *if* the patent laws, as they stand today, permit such claims. The rule that products of nature are not eligible subject matter rests not on the fact that they may not encompass a category of subject matter identified in Section 101, but that, pursuant to the product of nature doctrine, they are not the type of discoveries that the statute was enacted to protect.³⁵⁰ Although exceptions to patent ineligibility have been extended to process claims that implicate natural principles, natural entities and mathematical algorithms, the same does not hold true for mental steps. For these reasons, as the aforementioned cases reveal, any patent claim that equates to a mental process, or incorporates a mental step that is not equivalent to a mathematical algorithm, should be deemed ineligible subject matter pursuant to the product of nature doctrine.³⁵¹ The following questions provide guidance in analyzing patent claims that implicate mental processes.

1. Does the subject matter of the claim only contain mental steps?
2. If a claim contains both mental and physical steps, for each mental step, does the mental step require some mental activity apart from solving a mathematical equation?

If the answer to either question is in the affirmative, the claim must be denied as seeking ownership over a mental process. With respect to question two, to the extent the mental step equates to a mathematical algorithm, the questions in subpart III.B.3 must be examined.

³⁵⁰ *Flook*, 437 U.S. at 593.

³⁵¹ Claim language indicative of mental steps includes: determining, registering, counting, observing, measuring, comparing, recording and computing. *Abrams*, 188 F.2d at 167. Processes utilizing these terms have been determined to constitute patent-ineligible subject matter. *Id.*

5. Abstract Ideas

Over the years, courts have defined abstract ideas in various ways: as reciting a law of nature,³⁵² referring to a broad application of a law of nature without limitation,³⁵³ something that is vague and lacking specificity,³⁵⁴ or something that refers to the manipulation of intangible entities.³⁵⁵ Taken together, the common law reveals two separate concepts encompassed by the abstract idea category. The first, as described in *Morse*, refers to those patent claims that are not directed to some specific end, but rather claim ownership over a general concept.³⁵⁶ These claims seek ownership over a general principle, which may include an idea, natural principle or natural entity, rather than the application of a principle to some specific end.³⁵⁷ The second concept encompasses theories, be they mathematical in origin or otherwise, that have yet to be proven.³⁵⁸ For example, Newton had a notion that there existed some force that acted upon matter in a certain way – through experimentation and scientific analysis, he proved the existence of his conceptual idea to be the law of gravity.³⁵⁹ In other words, he brought an idea that he conjured in the abstract to the forefront by demonstrating the real-world applicability of the idea, such that the concept actually exists as a natural principle independent of man’s knowledge of the existence of the principle.

An idea is a concept that exists in the mind as a result of mental understanding, awareness or activity;³⁶⁰ it is a thought, conception, notion,

³⁵² See, e.g., *LeRoy*, 55 U.S. at 174-175.

³⁵³ See, e.g., *Morse*, 56 U.S. at 120.

³⁵⁴ See, e.g., *Rubber-Tip Pencil*, 87 U.S. at 507 (an idea is not patentable without some means of making the idea practically useful).

³⁵⁵ See, e.g., ROBINSON ON PATENTS, 1890 Edition, Vol. 1, p 230, cited in *Shao Wen Yuan*, 188 F.2d at 381. An art or operation is an act or a series of acts performed by some physical agent upon some physical object, and producing in such object some change either in character or condition. *Id.* “It is so far abstract that it is capable of contemplation by the mind apart from any one of the specific instruments by which it is performed. It is so far concrete that it consists in the application of physical force through physical agents to physical objects, and can thus become apparent to the senses only in connection with some tangible instrument and object. *Id.*”

³⁵⁶ *Morse*, 56 U.S. at 119.

³⁵⁷ *Id.* As Curtis explains, patent-eligible subject matter exists where one brings “a principle into practical application.” Curtis, *supra* note ___, at § 72, p 89.

³⁵⁸ See, e.g., *Rubber-Tip Pencil*, 87 U.S. at 507.

³⁵⁹ Alan Shapiro, Newton’s “Experimental Philosophy”, 9 *Early Science and Medicine* 185 (2004).

³⁶⁰ Oxford English Dictionary; other dictionary from 1800s

groundless supposition or fantasy.³⁶¹ Something that is abstract is set apart from concrete reality, specific objects or actual instances.³⁶² Taken together, abstract ideas are concept that express a quality or characteristic apart from any specific object or instance. In this respect, an abstract idea is some notion that is theoretical and not applied in practice. It is a “motive” to conduct further research, as the Court properly indicated in *LeRoy*.³⁶³

Abstract ideas do not necessarily implicate natural principles or natural entities. Rather, abstract ideas can also include ways of thinking about a certain task. For instance, I can think of a way to organize the outline of this article, or think about the best way to teach my Biotechnology Law & Policy students. These ideas, however, are akin to mental processes that do not recite mathematical equations, as noted in Part III.B.4 *infra*.

The proposed framework takes into account the various concepts that the abstract idea category encompasses. Accordingly, the following questions should be addressed to determine whether a claim amounts to an abstract idea:

1. Does the patent claim express a general concept without identifying a specific application of the concept?
2. If a patent claim identifies a specific application of a general concept, would issuance of the claim grant a property interest over anything beyond the scope of the specific application identified in the patent?
3. If a patent claim identifies a specific application of a general concept, would issuance of the claim preempt all known practical uses of the concept?
4. Does the patent claim express a concept that recites a theory regarding the existence or occurrence of a natural principle or natural entity?
5. Does the patent claim express a non-mathematical way of thinking about a certain task?

Overall, these five questions serve to capture the concepts encompassed by the abstract idea category. To the extent a patent claim fails to apply a general concept to some specific end, it is patent ineligible as seeking ownership over an abstract idea.³⁶⁴ For patent claims that apply a general concept to some specific end, patent eligibility is proper so long as the patent

³⁶¹ See *id.*

³⁶² See *id.*

³⁶³ *LeRoy*, 55 U.S. at 175.

³⁶⁴ See, e.g., *Morse*, 56 U.S. at 120.

claim does not preempt all known practical applications of the concept.³⁶⁵ If a patent claim expresses a concept that recites a theory regarding a natural principle or entity, the claim does not constitute patent eligible subject matter because it amounts to an attempt to patent a motive for further research, rather than a proven scientific truth.³⁶⁶ And, if a patent claim amounts to a way of thinking about a certain task, such that the claim is properly equated to a non-mathematical mental process, it is properly deemed ineligible subject matter for the reasons outlined in Part III.B.4.

IV. APPLICATION OF THE UNIFORM FRAMEWORK

The series of questions set forth in the proposed framework are structured to accurately embody the conceptual justifications for excluding subject matter pursuant to the product of nature doctrine. Coupled with this theoretical foundation, the questions serve as a practical and technology-agnostic method of identifying whether issuance of a particular claim would amount to a property interest over patent-ineligible subject matter. As highlighted, previous tests for patent eligibility have failed for a variety of reasons, which include comingling of statutory requirements and inconsistent results across a diverse range of technologies.

The applicability of the proposed framework is illustrated through examination of the following areas: traditional innovations, business methods and computer software, biomarkers, and stem cell technologies. Examining application of the proposed framework across these technologies highlights the advantages of the methodology, which include: (i) a simplified process of evaluating patent-eligible subject matter, (ii) an analysis that properly focuses the inquiry on the underlying subject matter claimed and (iii) a theoretical rationale that is appropriately grounded on an accurate harmonization of the constitutional mandate with the patent statute and subject matter jurisprudence.

A. *Traditional Inventions*

Under the heading of traditional inventions, I will apply the proposed framework to innovations that have been discussed throughout this Article. Recall in *LeRoy* where the Court examined the scope of patentability for an invention that applied a newly discovered property of lead to a particular method of lead manufacturing.³⁶⁷ Clearly, this claim qualifies as a process as

³⁶⁵ See, e.g., *Diehr*, 450 U.S. at 191-192.

³⁶⁶ See, e.g., *LeRoy*, 55 U.S. at 174-175.

³⁶⁷ *LeRoy*, 55 U.S. at 171-172.

defined in the patent statute.³⁶⁸ Further, to the extent the claim recites subject matter that refers to an empirical observation of physical behavior that describes an aspect of lead, which is a natural substance, the claim implicates a natural principle.³⁶⁹ Looking to the process-orientated claims of natural principles, the following observations unfold: (i) the natural principle that is encompassed in the claim is applied to a specific end, namely, a method of manufacturing lead pipes;³⁷⁰ (ii) the claim does not effectively grant a property interest in the natural principle, but rather is limited to the specific method identified in the claim;³⁷¹ (iii) the claim does not grant a property interest that extends to any other practical use of the natural principle;³⁷² and (iv) there is no evidence that the method, as a whole, is something that exists, or existed, in nature prior to the invention.³⁷³ For these reasons, under the proposed framework, the claim qualifies as patent-eligible subject matter.

Contrast the *LeRoy* invention with Morse's claim 8.³⁷⁴ Similar to *LeRoy*, Morse's claim 8 involves a process that implicates a natural principle. Unlike in *LeRoy*, however, Morse's claim is overly broad – specifically, claim 8 seeks ownership over any method of utilizing electromagnetism for making intelligible marks at a distance, despite the fact that Morse created only one method of doing so.³⁷⁵ Utilization of Natural Principle questions 3-6 reveals that Morse's claim 8 fails to qualify as patent-eligible subject matter because: (i) the natural principle is not applied to some specific end, but rather claims ownership over a general ability to make intelligible marks at a distance through use of electromagnetism;³⁷⁶ and (ii) if granted, the claim would foreclose others from utilizing the natural principle to make intelligible marks at a distance through any method other than the one that Morse invented.³⁷⁷ Bell's claim in *The Telephone Cases* is patent-ineligible subject matter for the same reasons.³⁷⁸

From process claims that implicate natural principles, I examined claims related to purified and isolated natural substances. The product claim in

³⁶⁸ *Id.*

³⁶⁹ See Natural Principle question 1.

³⁷⁰ See Natural Principle question 3.

³⁷¹ See Natural Principle question 4.

³⁷² See Natural Principle question 5.

³⁷³ See Natural Principle question 6.

³⁷⁴ *Morse*, 56 U.S. at 112.

³⁷⁵ *Id.*

³⁷⁶ See Natural Principle question 3.

³⁷⁷ See Natural Principle question 4.

³⁷⁸ *The Telephone Cases*, 8 S. Ct. at 782.

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American Wood Paper is patent-ineligible subject matter because the purified and isolated substance is not substantially different from substances that were known to have existed prior to the purification and isolation process of the applicant. Thus, the substance fails to pass muster under Natural Entity questions 1 and 6. Both the dye in *Cochrane* and the fiber in *Ex parte Latimer* constitute patent-ineligible subject matter for the same reasons. As to process claims, for *American Wood Paper*, *Cochrane*, and *Ex parte Latimer*, the process of purification or isolation is patent-eligible subject matter since (i) a patent on the process would not effectively grant a property interest in anything other than the claimed process and (ii) the claimed process is not something that exists, or existed, in nature prior to man's creation of the process.³⁷⁹ Contrary to the decisions of the lower courts in *Keuhmsted*, *Union Carbide*, *Parke-Davis*, the product claims in these cases, as well as the product claims in *General Electric*, constitute patent-ineligible subject matter, under Natural Entity question 6, because the products are not substantially different from their respective non-isolated or non-purified origins.

Applying the proposed framework to *Funk Brothers*, the product claims constitute patent-eligible subject matter because: (i) the combination of bacteria, which qualifies as a natural entity, is not claimed *per se*, but rather is applied to some specific end, namely, as an inoculant for leguminous plants; (ii) the products claims, as drafted, do not extend a property interest over the bacteria themselves, but rather are limited to use of the combined bacteria as an inoculant for leguminous plants; (iii) the product claims, as drafted do not grant a property interest in any additional practical use of the bacteria; and (iv) use of the combination of bacteria in a single inoculant did not exist prior to the patent application.³⁸⁰ Turning to Chakrabarty's bacteria, subject matter eligibility is supported under the proposed framework (i) to the extent man is the proximate cause of the existence of the new form of bacteria, (ii) Chakrabarty's bacteria are substantially different from any known bacteria and (iii) the bacteria is not something that existed in nature prior to Chakrabarty's work.³⁸¹

With respect to process claims that implicate mathematical algorithms and computer software, under the proposed framework, the process claims in *Benson* and *Bilski* constitute patent-ineligible subject matter, while the claims in *Flook* and *Diehr* are patent-eligible. In *Benson*, the mathematical algorithm does not express or represent a natural principle or entity, but rather is a man-created computation that assists a process relevant to many types of

³⁷⁹ See Natural Entity questions 12 and 13.

³⁸⁰ See Natural Entity questions 1, 4-7.

³⁸¹ See Natural Entity questions 1-3.

businesses.³⁸² Although the mathematical algorithm is applied to some specific end, issuance of the claims would grant a property interest in the algorithm itself, given the wording and structure of the claims, and thus would preclude all additional uses of the algorithm.³⁸³ The *Bilski* claims constitute patent-ineligible subject matter because (i) the claims identify a general concept without identifying a specific application of the concept, (ii) for those claims that identify a specific application of a general concept, the claims would grant a property interest in subject matter beyond the specific application identified in the patent, (iii) the claims represent a non-mathematical way of thinking about a certain task, and (iv) the claims contain mental steps that require mental activity apart from solving a mathematical equation.³⁸⁴

On the other hand, the *Flook* and *Diehr* processes constitute patent-eligible subject matter because the each claim: (i) applies a mathematical equation to a specific end; (ii) does not equate to a property interest over the equation itself; (iii) if granted, would not provide a property interest in the equation apart from use of the equation in connection with the remaining steps in the claim; and (iv) if granted, would not preclude any additional use of the underlying equation.³⁸⁵

Taken together, the proposed framework reveals that the Supreme Court's determination of subject matter ineligibility was improper in *Funk Brothers* and *Flook*, while lower court findings of patent eligibility were improper in *Keuhmsted*, *Union Carbide* and *Parke Davis*.

B. Business Methods and Computer Software

Business methods have a long and storied history in American patent law.³⁸⁶ The Patent Office has issued a large number of business method

³⁸² *Benson*, 409 U.S. at 64.

³⁸³ See Mathematical Algorithm questions 7-9.

³⁸⁴ See Abstract Idea questions 1-3, 5 and Mental Process question 2. The invalidation of the *Bilski* claims through use of the proposed framework is consistent with the rejection of the claims by the Patent Office. Specifically, the patent examiner rejected *Bilski*'s application because it "is not implemented on a specific apparatus and merely manipulates an abstract idea and solves a purely mathematical problem without any limitation to a practical application." The Board of Patent Appeals affirmed, concluding that "the application involved only mental steps" and that the claims are "directed to an abstract idea." *Bilski*, 130 S. Ct. at 3224.

³⁸⁵ See Mathematical Algorithm questions 6-9.

³⁸⁶ The fact that business method patents were not frequently granted prior to the late 1900s does not necessarily imply that business methods do not constitute patent-eligible

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patents, some of which date back to the early nineteenth century.³⁸⁷ As with any technology sector, not all business method patent claims have been deemed to constitute patent-eligible subject matter.

For example, in 1860, an appellate court denied patent protection, on subject matter and non-obviousness grounds, to a method of keeping mercantile accounts whereby a balance sheet and statement of assets and liabilities are constantly shown without consulting the ledger.³⁸⁸ Similarly, in 1908, the Second Circuit examined a patent on a method for cash-registering and account-checking that was designed to prevent fraud by cashiers and waiters in the restaurant and hotel businesses.³⁸⁹ The court acknowledged that the method qualified as an art under the patent statute, but argued that, since the claimed method was “disconnected from the means for carrying out the system”, it equated to an abstract idea, and thus was unpatentable.³⁹⁰

Early attempts were also made to patent business methods as machines. In a 1903 case, an applicant sought to patent a method for handling a large number of passengers who patronize public vehicles provided for rapid transit in large cities.³⁹¹ The court denied the patent, indicating that “no mere abstraction, no idea, however brilliant, can be the subject of a patent irrespective of the means designed to give it effect.”³⁹² This position was later echoed by the CCPA, which held that “a system of transacting business, apart from the means for carrying out the system, is not encompassed by the category process.”³⁹³ According to the CCPA, such a claim was akin to an

subject matter. Nothing in the legislative history demonstrates an intent to preclude eligibility for business methods, and a number of early business method patents were issued. It may be the case that early inventors elected not to seek patent protection for their business methods, but rather sought to maintain their inventions as trade secrets. There are ample benefits to maintaining business methods as trade secrets, most notably a lack of specified period after which the method enters the public domain.

³⁸⁷ These include: U.S. 871 “Bank Note” (issued Aug. 3, 1838) (process of engraving, printing or any way expressing the sum of large letters, words or figures on the face of a note); U.S. 1700 “Improvement in the Mathematical Operation of Drawing Lottery Schemes” (issued July 18, 1840) (process of making lottery tickets using an algorithm, diminishing the number of tickets and regulating the drawing); U.S. RE11,270 “Means for Insuring Travelers Against Loss by Accident” (filed July 21, 1892).

³⁸⁸ *Ex parte Dixon*, 7 F. Cas. 747, 748 (C.C.D.C. 1860).

³⁸⁹ *Hotel Security v. Lorraine*, 160 F. 467, 469 (2d Cir. 1908).

³⁹⁰ *Id.* The court also noted that the method was not new and did not exhibit inventive qualities. *Id.* at 471-472.

³⁹¹ *Fowler v. City of New York*, 121 F. 747, 748 (2d Cir. 1903).

³⁹² *Id.*

³⁹³ *In re Patton*, 127 F.2d 324, 327 (C.C.P.A. 1942).

abstract idea, which does not constitute eligible subject matter if it does not provide a means for carrying the idea into effect.³⁹⁴

The principles underlying these early decisions are fully incorporated into the product of nature doctrine. Attempts by courts to limit subject matter eligibility beyond the product of nature exclusions, through the creation of various eligibility tests, run contrary to the authority of the judiciary in framing patent doctrine and have served to unnecessarily complicate the Section 101 analysis. For these reasons, tests such as the “useful, concrete and tangible result” test and “machine-or-transformation” test, should be abandoned, and a framework based on the statutory categories and product of nature exclusions should be adopted. Furthermore, a wholesale exclusion for business methods is not supported by the statute or legislative history.³⁹⁵

Under the proposed framework, a business method claim should be analyzed to determine if the claim qualifies under a statutory category and does not violate the product of nature doctrine. It is anticipated that a number of business method claims will likely fail to constitute eligible subject matter because either (a) they include a mental process that does not qualify as an exclusion to the unpatentability of mental processes or (b) they amount to a claim over a general concept that is not applied to some specific end.³⁹⁶ It is further anticipated that, although many business methods will qualify as patent-eligible subject matter under the proposed framework, a significant number will ultimately fail to meet other statutory requirements.³⁹⁷

The patentability of computer software, both standing alone and as a component part of a business method, requires further analysis. At its core, computer software is a long series of commands that dictates whether a switch will be turned on-or-off.³⁹⁸ Any given computer is comprised of millions of such switches, and a computer program utilizes electrical signals to manipulate these switches.³⁹⁹ It is this computer-implemented process that is eligible for patent protection.⁴⁰⁰ Whereas software may be characterized as a series of

³⁹⁴ *Id.*

³⁹⁵ Compare *Bilski*, 130 S. Ct. at 3231 (Stevens, concurring in judgment).

³⁹⁶ See Mental Process question 2 and Abstract Idea question 1.

³⁹⁷ See *Bilski*, 130 S. Ct. at 3229 (insert parenthetical).

³⁹⁸ This is similar to Morse’s telegraph, which was comprised of a series of on/off switches that produced intelligible communications at a distance when the switches were manipulated in a certain manner.

³⁹⁹ Thomas J. Boardman, *The Future of Statistical Computing on Desktop Computers*, 36 *The American Statistician* 49 (1982).

⁴⁰⁰ See, e.g., Chung Pack, *Patenting E-Commerce Inventions: Perspective from an Administrative Patent Judge*, 85 *J. Patent & Trademark Office*, 447, 448-449 (2003).

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commands applied to a specific end, a given computer program may be defined as a method of activating switches in such a way that a desired result will be produced.⁴⁰¹

As indicated, a computer program itself is properly viewed as a process. To the extent a computer program does not express a natural principle or natural entity, or require a non-mathematical mental step, the natural principle, natural entity and mental process exclusions do not apply. Likewise, to the extent a program is created to be used in a specific way, it does not amount to an abstract idea. Under this scenario, computer programs constitute patent eligible subject matter. This fact notwithstanding, a significant percentage of programs may ultimately be deemed non-obvious, and thus patent protection may not ultimately be afforded.⁴⁰²

For these reasons, incorporation of a mathematical algorithm or computer program as a step of business method patent does not disqualify the method on subject matter grounds, so long as the claim, as a whole, does not violate the product of nature doctrine. As discussed, whether the patent laws should extend to business methods and computer programs must be distinguished from whether the current patent regime deems them to qualify as patentable subject matter.

C. Biomarkers

Life science companies are devoting significant resources to the study and development of health care products that are based on the detection or measurement of biomarkers.⁴⁰³ Biomarkers are newly discovered natural phenomena, such as genetic or physiological abnormalities, that correlate with the likelihood of developing a disease or the likelihood of receptiveness to a particular treatment.⁴⁰⁴ Biomarkers form an important component of many

⁴⁰¹ Indeed, over 100,000 software patents have been issued, and the Federal Circuit has endorsed the patentability of software without exception. Cohen and Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 3 (2001). As such, the question is not whether software patents should be issued, but which patents meet the statutory requirements. *Id.*

⁴⁰² Of course, copyright and trade secrecy are other avenues used to protect innovations in computer software. See generally John S. Paniaguas and Craig William Mandell, A Practitioner's Guide to Protecting Technology Assets, 20 DePaul J. Arts Tech. & Intell. Prop. L. 279 (2010).

⁴⁰³ See, e.g., Karin D. Rodland, Systems Biology and Biomarker Discovery, 28 Disease Markers 195 (2010); Willard, et al., Genomic Medicine: Genetic Variation and Its Impact on the Future of Health Care, 360 Philosophical Transactions: Biological Sciences 1543 (2005).

⁴⁰⁴ See *id.* (both).

clinical trials, and play a critical role in predicting disease and facilitating drug development.⁴⁰⁵ Use of biomarkers in the development of innovations in personalized medicine is particularly significant.⁴⁰⁶

The Patent Office has issued numerous biomarker patents.⁴⁰⁷ Despite issuance of such patents, the extent of patent protection for biomarkers remains hotly contested.⁴⁰⁸ One of the most widely discussed biomarker patent cases is *Laboratory Corp. of America v. Metabolite Laboratories, Inc* (hereinafter

⁴⁰⁵ See *id* (both).

⁴⁰⁶ See *id* (both).

⁴⁰⁷ Statistics from the USPTO reveal that hundreds of biomarker patents have been issued.

⁴⁰⁸ See, e.g., Durham, *supra* note __, at 934; Collins, *supra* note __, at 360-362; Klein, *supra* note __, at 148.

“*LabCorp*”).⁴⁰⁹ Whereas the details of *LabCorp* have been extensively discussed,⁴¹⁰ I will focus solely on analyzing the claim-at-issue:

13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
 assaying a body fluid for an elevated level of total homocysteine; and
 correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

There can be no question that the fact that total homocysteine (“TH”) correlates with vitamin deficiency is a natural principle. On its face, however, claim 13 does not recite ownership over the correlation. Rather, claim 13 is drafted as a process claim for detecting this natural principle.

⁴⁰⁹ In the 1980s, three university doctors, after conducting research into vitamin deficiencies, found a correlation between high levels of homocysteine in the blood and deficiencies of two essential vitamins, folate (folic acid) and cobalamin (vitamin B12). The doctors then patented innovations related to their research. Metabolite, a licensee of that patent, entered into a sublicense agreement with LabCorp. Until 1998, LabCorp used the patented tests and paid royalties to Metabolite. By the late 1990s, research revealed that elevated homocysteine levels could predict risk of heart disease. This led to increased testing for homocysteine, and the creation of alternative testing procedures. LabCorp decided to use one of the alternative tests, but continued to pay royalties to Metabolite when it used the Metabolite test. In response, Metabolite filed a patent infringement lawsuit against LabCorp.

Whereas Congress afforded doctors immunity for patent infringement suits, Metabolite argued that LabCorp, by advertising its tests, providing doctors with test results and educating doctors about the correlation, was liable for inducing doctors to infringe. The jury returned a verdict against LabCorp on this theory, and the Federal Circuit affirmed. Notably, the Federal Circuit did not address LabCorp’s argument that claim 13 violates the product of nature doctrine. Although LabCorp put forth this argument, it failed to cite specifically to Section 101 of the Patent Act, and thus the lower courts did not discuss the relevance of Section 101. As a result, the Supreme Court dismissed the writ of certiorari as improvidently granted. Justice Breyer, with whom Justice Stevens and Justice Souter joined, dissented from the dismissal, and argued that claim 13 should be invalidated for failing to state patent eligible subject matter.

In his dissent, Justice Breyer begins by indicating that defining the categories of the product of nature doctrine is difficult. At one point in his dissent, Justice Breyer analyzes claim 13 as a process involving two steps: obtaining test results and thinking about them. At another, he indicates that the claim amounts to a description of a natural principle. Thus, for Justice Breyer, it appears the claim should be invalidated on statutory subject matter grounds because the claim (1) includes a mental step or (2) seeks ownership over a natural principle. The framework proposed in this paper supports both of these positions.

⁴¹⁰ See, e.g., Durham, *supra* note __, at 934; Collins, *supra* note __, at 360-362; Klein, *supra* note __, at 148.

A close reading of the claim reveals that the method of detection is not limited in any way. Rather, the claim seeks ownership over all methods of measuring TH and analyzing the test results. As the parties agreed during the litigation, the claim is not limited to the specific test created by the applicants, but rather extends to any test that may be used to observe the chemical level.⁴¹¹ In this respect, claim 13 asserts ownership beyond the method of detection invented by the applicants. Not only does the claim extend to methods of detection not created by the applicants, since the claim asserts ownership over all methods of detection and analysis of TH, the claim preempts all practical uses of the underlying natural principle.⁴¹² Accordingly, the claim essentially grants a property interest in the natural principle itself. Although the three university doctors may have been the first to uncover this natural principle, they surely did not create the significance of the correlation.

Furthermore, assuming the claim limited the method to the test created by the applicants and there were other methods of observing the natural principle, under the proposed framework, the claim still would constitute ineligible subject matter because of the type of mental step recited in the claim. Namely, the claim requires correlation of TH with the existence of a vitamin deficiency. As Metabolite admits, since the natural relationship between TH and vitamin deficiency is well known, the correlating step would automatically occur in the mind of any competent physician. Since this type of mental step does not qualify as an exception to the product of nature exclusion for patents claiming mental processes, the claim does not constitute patent eligible subject matter.⁴¹³ Under the proposed framework, Natural Principle questions 4-5 and Mental Process question 2 guide the determination of patent ineligibility of claim 13.

As noted, following its ruling in *Bilski*, the Supreme Court ordered that the Federal Circuit reexamine its holding in *Prometheus v. Mayo*. *Prometheus* is a biomarker case, and a representative claim reads:

⁴¹¹ *LabCorp*, 548 U.S. at 130.

⁴¹² See Natural Principle questions 4-5.

⁴¹³ See Mental Process question 2.

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

- (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
- (b) determining a level of 6-thioguanine or 6-methylmercaptapurine in said subject having said immune-mediated gastrointestinal disorder,

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

wherein a level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells or a level of 6-methylmercaptapurine greater than about 7000 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

This claim may be translated as follows: A method of treating a patient with a gastrointestinal disorder by administering a drug, measuring the effect of the drug and adjusting the dosage based on the patient's response to the previous dosage. This claim fails to recite eligible subject matter because, as with the *Metabolite* claim, the mental step (the determining step) of the claim is not encompassed by an exception to the unpatentability of mental processes.⁴¹⁴ Thus, under the proposed framework, the claim is patent ineligible pursuant to Mental Process question 2.

The failure of the aforementioned *Metabolite* and *Prometheus* claims to satisfy the subject matter eligibility framework proposed in this paper does not imply that all patent claims related to biomarkers are patent ineligible. As discussed, the scope of patentable subject matter is quite broad, and provides rights over new drugs, diagnostic tests and methods of diagnosing a particular disease. However, subject matter eligibility does not extend to claims that equate to ownership over a natural principle, claims that fail to apply a natural principle to some specific end, or claims that equate to a physician's consideration of a scientific fact.

D. *Stem Cell Technologies*

The use of public funds to support stem cell research has received far greater publicity than the government's encouragement of research through

⁴¹⁴ See Mental Process question 2.

issuance of stem cell patents.⁴¹⁵ Though competing biotechnology companies often allege infringement of issued stem cell patents,⁴¹⁶ and scholars debate moral and economic issues surrounding stem cell research,⁴¹⁷ discussion of subject matter eligibility for stem cell technologies has received modest attention. This is despite the fact that over 1,700 stem cell patents have been issued.⁴¹⁸

Following *Chakrabarty* and subsequent breakthroughs in stem cell technologies, commentators began to fear that the patent laws could be utilized to gain property interests in humans or human-animal chimeras.⁴¹⁹ In 1987, as a response to these fears, the Patent Office argued that there is a constitutional basis for precluding patent protection for property interests in “human beings” where the “broadest reasonable interpretation” of a patent claim could be read as encompassing a “human being”.⁴²⁰ Ironically, that same year, the Patent Office issued a patent to Johns Hopkins University titled “Human Stem Cells”.⁴²¹

The ban on “human being” patents was expanded in 2004. Seeking additional methods of limiting research in controversial areas such as embryonic stem cell research, lawmakers passed what is now known as the Weldon Amendment.⁴²² Part of the appropriations bill for 2004, the Weldon Amendment requires that “none of the funds appropriated or otherwise made available by this act may be used to issue patents on claims directed to or

⁴¹⁵ See Bagley, *supra* note __, at 469.

⁴¹⁶ See, e.g., Mills and Tereskerz, Empirical Analysis of Major Stem Cell Patent Cases, 28 *Nature Biotechnology* 325 (2010); Shyntum and Kalkreuter, Stem Cell Patents – Reexamination/Litigation – the Last 5 Years, 15 *Tissue Engineering* 87 (2009).

⁴¹⁷ See, e.g., John A. Robertson, Embryo Stem Cell Research: Ten Years of Controversy, 38 *J. of Law, Medicine and Ethics* 191 (2010); Richard M. Doerflinger, Old and New Ethics in the Stem Cell Debate, 38 *J. of Law, Medicine and Ethics* 212 (2010); Todd Spalding and Michelle Simkin, 19 *Intell. Property & Tech. L.J.* 7 (2007).

⁴¹⁸ See, e.g., Spalding and Simkin, How Will Patents Impact the Commercialization of Stem Cell Therapeutics?, 19 *Intellectual Property & Technology L.J.* 7 (2007); Tao Huang, Stem Cell Patent Landscape and Patent Strategy, in *Trends in Biopharmaceutical Industry*, at 43 (accessed August 21, 2010). Along with the issued patents, the Patent Office has published over 6,000 stem-cell related patent applications. See Huang, *supra* at 43.

⁴¹⁹ See, e.g., Alan Pampidou, Research on the Human Genome and Patentability: The Ethical Consequences, 21 *Journal of Medical Ethics* 69, 70 (1995).

⁴²⁰ See Thomas Magnani, The Patentability of Human-Animal Chimeras, 14 *Berk. Tech. L.J.* 443, 449 (1999).

⁴²¹ U.S. Patent 4,714,680.

⁴²² See Timothy Holbrook, The Expressive Impact of Patents, 84 *Wash. U. L. Rev.* 573, 599 (2006).

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encompassing a human organism.”⁴²³ Whereas the Patent Office receives its government funding through the appropriations bill, the Weldon Amendment seeks to preclude the office’s ability to issue patents on “human organism” claims. Although some have questioned the validity of the prohibition,⁴²⁴ the Weldon Amendment has been reinstated in the appropriations bill every year since 2004.⁴²⁵

Current laws provide little guidance in defining the phrases “human being” or “encompassing a human organism”, and a significant number of issued patents arguably fall under these definitions.⁴²⁶ For example, the Wisconsin Alumni Research Foundation, a non-profit foundation that manages intellectual property generated by researchers at the University of Wisconsin, owns three patents that provide a property interest over a method of isolating human embryonic stem cells, as well as the resultant stem cell lines, on research derived from experiments on human blastocysts.⁴²⁷ During reexamination, the Patent Office initially raised an issue of non-obviousness, which the patent holders were eventually able to overcome.⁴²⁸ A subject matter objection was not discussed.⁴²⁹ Subsequent reexamination of the patents resulting in an office action that recommended invalidation; however, this invalidation was solely based on non-obviousness grounds.⁴³⁰ The reexamination proceeding is still pending, and a final judgment may not come until after the patents have expired.⁴³¹

Of the thousands of issued claims related to stem cell technologies, the following is a representative sample of subject matter the Patent Office has

⁴²³ Consolidated Appropriations Act of 2004, Pub. L. No. 108-109 § 634, 118 Stat. 3, 101 (2004).

⁴²⁴ cite

⁴²⁵ See O. Carter Snead, Public Bioethics and the Bush Presidency, 32 Harvard J.L. Public Policy 867, 887 n.62 (2009); Consolidated Appropriations Act 2010, P.L. 111-117, Title V, Section 518, 123 STAT 3153 (Dec. 16, 2009).

⁴²⁶ Particularly if one classifies a human embryo as equating to, or encompassing, human life. For instance, since 2004, the Patent Office has issued hundreds of patents that encompass human stem cells or methods associated with human stem cell technologies.

⁴²⁷ See, e.g., John M. Golden, WARF’s Stem Cell Patents and the Tensions between Public and Private Sector Approaches to Research, 38 J. Law, Medicine and Ethics 314 (2010).

⁴²⁸ See id.

⁴²⁹ See id. The failure to adequately analyze subject matter eligibility has also plagued genomic and proteomic patents. See Berman and Dreyfuss, *Reflections on the Science and Law of Biology, Genomics and Drug Development*, 53 UCLA L. REV. 871, 889 (2006).

⁴³⁰ See BPAI decision, dated April 28, 2010, available at <http://pub.bna.com/ptcj/101854Apr28.pdf>. See also PTO Finds Stem Cell Patent Anticipated, Obvious in Light of ‘Significant Guideposts’, BNA Reports, May 4, 2010.

⁴³¹ See PTO Finds Stem Cell Patent Anticipated, Obvious in Light of ‘Significant Guideposts’, BNA Reports, May 4, 2010.

deemed to be patent-eligible: (1) methods of cloning stem cells;⁴³² (2) methods of isolating stem cells;⁴³³ (3) methods of purifying stem cells;⁴³⁴ (4) treatment methods utilizing stem cells;⁴³⁵ (5) methods of stimulating the growth, proliferation or differentiation of stem cells;⁴³⁶ (6) devices for detecting, maintaining, separating and culturing stem cells;⁴³⁷ and (7) stem cells and stem cell lines.⁴³⁸

Stem cell technologies provide an ideal paradigm for illustrating the contours of the proposed framework. Subject matter eligibility would extend to methods of (i) isolating or purifying stem cells, (ii) cloning stem cells and (iii) stimulating the growth, proliferation or differentiation of stem cells, so long as (a) the claimed method itself is not equivalent to a method that occurs in nature,⁴³⁹ (b) the method does not provide a property interest in any underlying natural principle or entity,⁴⁴⁰ (c) the property interest awarded through issuance of the claim is limited to the method created and described by the applicant,⁴⁴¹ (d) the claimed method is not the sole process by which the stem cells can be isolated or purified,⁴⁴² and (e) the method does not include a non-mathematical mental step.⁴⁴³ Similarly, devices for detecting, maintaining, separating and culturing stem cells are patentable subject matter so long as the claim is limited to the device created by the applicant and issuance of the claim would not extend a property interest over the stem cells or any naturally-occurring property of the cells.⁴⁴⁴

Claims over purified or isolated stem cells are ineligible where the purified or isolated stem cells are not substantially different from their non-isolated or non-purified counterparts, or where natural properties of the cells are the proximate cause of any distinction between the subject matter of the

⁴³² U.S. Patent 7,531,715.

⁴³³ U.S. Patent 5,061,620; U.S. Patent 5,639,618.

⁴³⁴ U.S. Patent 6,852,533.

⁴³⁵ U.S. Patent 7,560,102.

⁴³⁶ U.S. Patent 7,524,500; U.S. Patent 7,423,029; U.S. Patent 7,135,459; U.S. Patent 7,442,394.

⁴³⁷ U.S. Patent 7,519,409; U.S. Patent 5,763,194; U.S. Patent 5,635,387; U.S. Patent 5,514,340; U.S. Patent 5,459,069.

⁴³⁸ U.S. Patent 7,560,275; U.S. Patent 6,852,533.

⁴³⁹ See Natural Principle question 6 and Natural Entity question 13.

⁴⁴⁰ See Natural Principle question 4 and Natural Entity question 5.

⁴⁴¹ See Natural Principle question 5 and Natural Entity question 6.

⁴⁴² See Natural Entity question 12.

⁴⁴³ See Mental Process question 2 and Abstract Idea question 5.

⁴⁴⁴ See Natural Entity question 12 and Abstract Idea questions 1-2.

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isolated or purified stem cell from the non-isolated or non-purified cells.⁴⁴⁵ Likewise, stem cell lines constitute ineligible subject matter to the extent natural properties govern the existence of the cell lines or are the proximate cause of any distinction between the cell lines and naturally-occurring cells.⁴⁴⁶ A treatment method utilizing stem cells constitutes eligible subject matter so long as the claim (a) applies stem cells to some specific end, (b) does not preempt use of the underlying naturally-occurring cells and (c) does not include a non-mathematical mental step.⁴⁴⁷ Such claims must also be drafted so as to not provide a property interest in anything other than the specific end created by the inventor.⁴⁴⁸

CONCLUSION

As recent cases and controversies reveal, there is an immediate need to clarify patent law so as to advance resolution of its most fundamental question – clear identification of the types of inventions that constitute patent-eligible subject matter. From repeated comingling of statutory requirements to blatant disregard for controlling authority, courts and the Patent Office have significantly deviated from the obligation to permit patentable subject matter only where an invention fits into a statutory category and does not violate the product of nature doctrine.⁴⁴⁹ Harmonizing these core principles requires a uniform framework that appropriately integrates the public policy underlying the patent statute and the theoretical basis for the product of nature doctrine.

The Supreme Court has consistently grounded patent jurisprudence in historical context,⁴⁵⁰ declining invitation to abandon long-standing doctrines

⁴⁴⁵ See Natural Entity questions 2-3, 8-11.

⁴⁴⁶ *Id.*

⁴⁴⁷ See Natural Entity questions 4-6, Mental Process question 2 and Abstract Idea questions 1-5.

⁴⁴⁸ *Id.*

⁴⁴⁹ As at least one court has observed, the “mass of testimony” frequently presented in patent-related matters often leads to a failure to understand “the comparatively simple statutory enactments regulating the grant of patents.” *Electric Smelting v. Carborundum*, 83 F. 492, 493 (W.D. Pa. 1897).

⁴⁵⁰ It is our duty to construe the patent statutes as they now read, in light of our prior precedents. *Deepsouth*, 406 U.S. at 531. For instance, in 1952, when Congress amended the patent statute to include nonobviousness, it reached back to *Hotchkiss v. Greenwood*, 52 U.S. 248 (1850) for guidance. Similarly, in deciding *Flook*, the Court noted that “to a large extent our conclusion is based on reasoning derived from opinions written before the modern business of developing programs for computers was conceived.” *Flook*, 437 U.S. at 596.

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even in the face of technological change.⁴⁵¹ The same approach should be adopted in defining patent-eligible subject matter. The proposed framework is comprised of accurate characterizations of the statutory categories and straightforward questions that properly capture the essence of each product of nature category. In structuring technology-agnostic questions, my goal is to provide a simple and flexible approach to determining whether a particular invention recites patentable subject matter.

The framework set forth in this Article seeks to recalibrate the debate surrounding how subject matter eligibility is analyzed and determined.⁴⁵² The framework not only accurately identifies those inventions that are products of nature, it properly bases patent ineligibility on the subject matter of the claims. The uniformity of the methodology is evidenced by the similarity of the questions across all categories.⁴⁵³ Whereas the proposed questions represent one method of defining each product of nature category, to the extent application of the methodology reveals any limitation, alternative questions may be adopted.

As the Supreme Court has highlighted, patent law does not serve to propertize thoughts, scientific knowledge, or pre-existing natural principles or entities. Rather, the function of patent law is to add to the sum of useful knowledge, and its purpose is to provide an incentive to disclose information to the public.⁴⁵⁴ To the extent current patent doctrine produces unintended or ill-

⁴⁵¹ *Microsoft*, 550 U.S. at 444 (relying on *Brown v Duchesne*, 60 U.S. 183 (1857)); *Pfaff v Wells*, 525 U.S. 55, 62 (1998) (applying *The Telephone Cases* (1888) to computer chip design case). Further, as the Court has recently indicated, the existence of the product of nature exceptions to statutory subject matter does not give the judiciary “*carte blanche* to impose other limitations that are inconsistent with the text and the statute’s purpose and design.” *Bilski*, 130 S. Ct. at 3226.

⁴⁵² Resolution of the legal requirements for subject matter eligibility will in turn permit a more informed discussion on the normative implications of the patent laws.

⁴⁵³ As Professors Nard and Duffy perceptively note, “uniformity is not a proxy for quality.” Craig Allen Nard and John F. Duffy, *Rethinking Patent Law’s Uniformity Principle*, 101 *Northwestern L. Rev.* 1619, 1620 (2007). Rather, the material issue is whether the patent laws accurately reflect the purpose and function underlying the federal grant of patents and provide “predictable rules capable of curtailing litigation costs.” *Id.* Mindful of these principles, the proposed framework does not seek uniformity for uniformity’s sake, but rather views uniformity, coupled with a practical application of the appropriate theoretical foundation, as the preferred method of structuring the patent laws so as to harmonize the underlying public policy with the realities of the marketplace.

⁴⁵⁴ *Bonito Boats*, 489 U.S. at 144. See also *LabCorp*, 548 U.S. at 126-127 (Breyer, dissenting from dismissal of writ as improvidently granted); *Farr Co. v. American Air Filter Co.*, 318 F.2d 500 (9th Cir. 1963); *Valmont Industries, Inc. v. Yuma Mfg. Co.*, 296 F. Supp. 1291 (D. Col. 1969).

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suiting consequences, Congress can amend the laws so as to further the public policy goals underlying the constitutional mandate.⁴⁵⁵

Defining the contours of patentable subject matter has proven to be one of the most difficult and controversial issues in patent law.⁴⁵⁶ The challenges raised by emerging biotechnologies, coupled with a general lack of understanding of science on the part of the judiciary,⁴⁵⁷ require a practical and robust framework for determining patentable subject matter. The fundamental objective of the proposed methodology is to guide patent doctrine down the proper path towards establishing a uniform framework for patent eligibility.

APPENDIX A

Framework for Determining if a Claim Implicates the Product of Nature Doctrine

NATURAL PRINCIPLES	
1.	Does the claim recite subject matter that refers to an empirical observation of physical behavior that describes an aspect of the universe?
YES:	Since a natural principle is implicated in the patent claim, must address Natural Principle questions 3-6.

⁴⁵⁵ See, e.g., Burk and Lemley, *supra* note __ at __ (explaining use of policy levers in framing patent legislation).

⁴⁵⁶ See Durham, *supra* note __, at 977; Duffy, *supra* note __, at 615.

⁴⁵⁷ See Andrew Jurs, *Judicial Analysis of Complex and Cutting-Edge Science in the Daubert Era*, 42 CONN. L. REV. 49, 70-71 (2009); Sean Seymore, *Serendipity*, 88 N.C. L. REV. 185, 187 (2009).

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	NO:	Proceed to Natural Principle question 2.
2.	Does the claim recite subject matter that refers to any state or process in the universe that occurs or exists independent of man's knowledge of its existence, or that arises without man's assistance?	
	YES:	Since a natural principle is implicated in the patent claim, must address Natural Principle questions 3-6.
	NO:	Natural principle component of the product of nature doctrine does not apply.
3.	If a natural principle is encompassed as part of a patent claim, is the natural principle applied to some specific end?	
	YES:	Proceed to Natural Principle question 4.
	NO:	Claim is patent ineligible subject matter under product of nature doctrine.
4.	Would a patent on such a claim grant a property interest that effectively extends to the natural principle itself, apart from the specific end identified in the claim?	
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Proceed to Natural Principle question 5.
5.	Would a patent on such a claim grant a property interest that extends to any additional practical use of the natural principle?	
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Proceed to Natural Principle question 6.
6.	Is the application of the natural principle that is claimed in the patent something that exists, or existed, prior to man's creation of the application?	
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Natural principle component of the product of nature doctrine does not apply.
NATURAL ENTITIES		
1.	Does the claim recite subject matter that refers to a living or non-living organism or substance that exists in the universe?	
	YES:	For any claim that does not recite an application of a natural entity, must address Natural Entity questions 2-3. For all claims that recite an application of a natural entity, must address Natural Entity questions 4-7. If the claim recites a product that refers to an isolated or purified natural substance, must address Natural Entity questions 2-3 and 8-11. If the claim recites a process that refers to a method of isolation or purification, must only address Natural Entity questions 12-13.
	NO:	Natural entity exception under product of nature doctrine does not

		apply.
2.	Is man the proximate cause of the existence of the living or non-living thing?	
	YES:	Proceed to Natural Entity question 3.
	NO:	Claim is patent ineligible subject matter under product of nature doctrine.
3.	Does the claimed natural entity exhibit characteristics or contain properties that are substantially different from any known living or non-living organism or substance?	
	YES:	Natural entity component of the product of nature doctrine does not apply.
	NO:	Claim is patent ineligible subject matter under product of nature doctrine.
4.	If a natural entity is encompassed as part of a claim, is the natural entity applied to some specific end?	
	YES:	Proceed to Natural Entity question 5.
	NO:	Claim is patent ineligible subject matter under product of nature doctrine.
5.	Would a patent on such a claim grant a property interest that effectively extends to the natural entity itself, apart from the specific end identified in the claim?	
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Proceed to Natural Entity question 6.
6.	Would a patent on such a claim grant a property interest that extends to any additional practical use of the natural entity?	
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Proceed to Natural Entity question 7.
7.	Is the application of the natural entity that is claimed in the patent something that exists, or existed, prior to man's creation of the application?	
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Natural entity component of the product of nature doctrine does not apply.
8.	Does the purified or isolated substance exhibit characteristics or contain properties that are substantially different from the non-purified or non-isolated substance?	
	YES:	Proceed to Natural Entity question 9.
	NO:	Claim is patent ineligible subject matter under product of nature doctrine.
9.	Is the proximate cause of the difference between the purified and non-purified substances the result of natural phenomenon that govern the properties of the substance when purified?	

	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Proceed to Natural Entity question 10.
10.		Is the proximate cause of the difference between the isolated and non-isolated substances the result of natural phenomenon that govern the properties of the substance when isolated?
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Proceed to Natural Entity question 11.
11.		Would a patent on the isolated or purified substance grant a property interest that extends to the non-isolated or non-purified substance?
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Natural entity component of the product of nature doctrine does not apply.
12.		Would a patent on a process of purification or isolation grant a property interest that effectively extends to subject matter apart from the process created by the applicant?
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Proceed to Natural Entity question 13.
13.		Is the process of purification or isolation that is claimed in the patent something that exists, or existed, prior to man's creation of the process?
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Natural entity component of the product of nature doctrine does not apply.
MATHEMATICAL ALGORITHMS		
1.		Does the mathematical algorithm express or represent a natural principle or natural entity?
	YES:	Proceed to Mathematical Algorithm question 2.
	NO:	Proceed to Mathematical Algorithm question 6.
2.		If a mathematical algorithm represents a natural principle or entity and is encompassed as part of a process, is the algorithm applied to some specific end?
	YES:	Proceed to Mathematical Algorithm question 3.
	NO:	Claim is patent ineligible subject matter under product of nature doctrine.
3.		Would a patent on the process grant a property interest that effectively extends to the natural principle or entity expressed in the algorithm, apart from the specific end identified in the patent claim?

	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Proceed to Mathematical Algorithm question 4.
4.	Would a patent on the process grant a property interest that effectively extends to any additional practical use of the mathematical algorithm?	
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Proceed to Mathematical Algorithm question 5.
5.	Is the application of the algorithm that is claimed in the patent something that exists, or existed, prior to man's creation of the application?	
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Mathematical algorithm component of the product of nature doctrine does not apply.
6.	Does the patent claim apply a mathematical equation to some specific end?	
	YES:	Proceed to Mathematical Algorithm question 7.
	NO:	Claim is patent ineligible subject matter under product of nature doctrine.
7.	Would granting the patent claim provide a property interest in a mathematical equation?	
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Proceed to Mathematical Algorithm question 8.
8.	Would granting the patent claim provide a property interest in a mathematical equation apart from use of the equation in connection with the remaining steps of the claim?	
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Proceed to Mathematical Algorithm question 9.
9.	Would granting the patent claim preclude any additional use of the mathematical equation?	
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Mathematical algorithm component of the product of nature doctrine does not apply.
MENTAL PROCESSES		
1.	Does the subject matter of the claim only contain mental steps?	
	YES:	Claim is patent ineligible subject matter under product of nature doctrine.
	NO:	Proceed to Mental Process question 2.
2.	If a claim contains both mental and physical steps, for each mental step, does the mental step require some mental activity apart from solving a mathematical	

	equation?
YES:	Claim is patent ineligible subject matter under product of nature doctrine.
NO:	Mental process component of the product of nature doctrine does not apply.
ABSTRACT IDEAS	
1.	Does the patent claim express a general concept without identifying a specific application of the concept?
YES:	Claim is patent ineligible subject matter under product of nature doctrine.
NO:	Proceed to Abstract Idea question 2.
2.	If a patent claim identifies a specific application of a general concept, would issuance of the claim grant a property interest over anything beyond the scope of the specific application identified in the patent?
YES:	Claim is patent ineligible subject matter under product of nature doctrine.
NO:	Proceed to Abstract Idea question 3.
3.	If a patent claim identifies a specific application of a general concept, would issuance of the claim preempt all known practical uses of the concept?
YES:	Claim is patent ineligible subject matter under product of nature doctrine.
NO:	Proceed to Abstract Idea question 4.
4.	Does the patent claim express a concept that recites a theory regarding the existence or occurrence of a natural principle or natural entity?
YES:	Claim is patent ineligible subject matter under product of nature doctrine.
NO:	Proceed to Abstract Idea question 5.
5.	Does the patent claim express a non-mathematical way of thinking about a certain task?
YES:	Claim is patent ineligible subject matter under product of nature doctrine.
NO:	Abstract idea component of the product of nature doctrine does not apply.

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