WHAT SHOULD BE PATENTABLE?—A PROPOSAL FOR DETERMINING THE EXISTENCE OF STATUTORY SUBJECT MATTER UNDER 35 U.S.C. SECTION 101

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The question of what type of inventions should be protectable under patent law is a controversial issue that has received significant attention. Recent Supreme Court decisions reject a bright-line test in favor of a more open-ended approach to determining patent eligibility. Unfortunately, this provides limited guidance to lower courts and consequently the issue remains unsettled. This article will examine the scope of patent-eligible subject matter defined by Patent Law section 101. It will look at judicial interpretation of the statute including exceptions judicially engrafted into the statute by the Supreme Court. Additionally, the competing policy concerns underlying the statute will be examined. It will be argued that this statute should be analyzed, interpreted, and applied consistently with the usual rules generally applied by courts. This requires understanding that underlying policies are often inconsistent or competing. Such policies must therefore be balanced in crafting an applicable rule. Any resulting rule will be imperfect because it will potentially be over- or under-inclusive. Additionally, it will have disproportionate effects on different industries. Nevertheless, the importance of a uniform and predictable rule outweighs these deficiencies. Rather than propose a single rule, several rules gleaned from Supreme Court decisions will be proposed in light of the fact that patents cover many different technologies and patent claims can be drafted in a multitude of ways. Violation of any of the proposed rules means the patent claim at issue is not patent-eligible subject matter.
I. INTRODUCTION

The question of what type of inventions should be protectable under patent law is a controversial issue that has received significant media attention. It has also been addressed in scholarly commentary. Moreover, it has been addressed by the U.S. Supreme Court and the Federal Circuit in numerous decisions. Despite this attention, the issue is still unsettled. Recent Supreme Court decisions suggest a desire by the Court to restrict the expansion of patentable subject

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1 See, e.g., Adam Liptak, Supreme Court Hears Case on Patents for Individualized Medicine, N.Y. TIMES, Dec. 8, 2011, at B3; Jackie Crosby, Patent Case has High Stakes for Medical Tests, MINN. STAR TRIBUNE, July 3, 2011, at 1D.


4 See, e.g., In re Comiskey, 554 F.3d 967, 969-70 (Fed. Cir. 2009) (holding that a method for resolving a dispute via arbitration standing alone was not patentable subject matter); In re Nuijten, 500 F.3d 1346, 1357 (Fed. Cir. 2007) (holding that electromagnetic signals are not patentable subject matter).

matters. However, those decisions appear to reject a bright-line test in favor of a more open-ended philosophical approach. Unfortunately, this provides limited guidance to lower courts and consequently the issue continues to be unsettled. Moreover, it is unclear if all the judges on the U.S. Court of Appeals for the Federal Circuit, which hears virtually all appeals in patent disputes, fully agree with this restrictive trend.

Most inventions fit within the statutory requirements defining patent-eligible inventions. Often, assertions that an invention falls outside this requirement arise when new technology gains economic importance. The advent of software as an important freestanding industry generated significant litigation with regard to whether software should be eligible for patent protection. Research and development work in the biotech industry raised the question of whether patents should be granted for isolated genetic material and

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6 See generally Mayo Collaborative Servs., 132 S. Ct. at 1301 (“The Court has repeatedly emphasized . . . a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature.”).

7 In Bilski v. Kappos, 130 S. Ct. 3218, 3227 (2010), the Supreme Court rejected the Federal Circuit’s reliance on the machine or transformation test as the sole test to determine whether a process is patent eligible. The Court held that the test is merely a clue or investigative tool for determining patent eligibility of a process. Id. The Court then rejected the adoption of categorical rules for determining patent eligibility. Id. at 3229-30.

8 See generally Asher Hodes, Diagnosing Patentable Subject Matter, 26 BERKELEY TECH. L.J. 225, 228-29 (2011) (finding that many commentators have noted the limited guidance given to lower courts by the Supreme Court decision in Bilski v. Kappos).


11 See generally AMY LANDERS, UNDERSTANDING PATENT LAW § 23.01, at 298 (2d ed. 2012) (writing that what is patent-eligible subject matter tends to be an issue when new areas of technology produce patent claims that differ from precedent).


for living microorganisms created in a laboratory.\textsuperscript{14} The patentability of software-based business methods utilized in the financial services industry\textsuperscript{15} and in Internet commerce created controversy.\textsuperscript{16}

Patents have taken on increased economic importance today.\textsuperscript{17} Enterprises use patents defensively by amassing patent portfolios to protect a technology space for future technology development.\textsuperscript{18} Likewise, they are used offensively to protect existing market share.\textsuperscript{19}

\textsuperscript{14} See Diamond v. Chakrabarty, 447 U.S. 303 (1980) (holding in a 5-4 decision that a living, manmade microorganism is patentable subject matter).
\textsuperscript{17} See generally Andrew J. Sherman, \textit{Fueling Rapid Growth Enterprises}, TECHAMERICA FOUNDATION, at 4 (July 2012), \textit{available at} http://www.techamericafoundation.org/content/wp-content/uploads/2012/07/Sherman-Fueling_Rapid_Growth_Enterprises.pdf (“It is now estimated that 80 percent of the market value of the S&P 500 companies is due to intangible assets, compared to just 20 percent for physical and financial assets.”); Nick Timiraos, \textit{Business Battle Over Patent Laws}, WALL ST. J., June 9, 2007, at A7 (stating that about one third of the value of all U.S. stocks is currently comprised of intangible assets which includes intellectual property).
\textsuperscript{18} See generally Stuart Graham & Ted Sichelman, \textit{Why Do Start-Ups Patent?}, 23 BERKELEY TECH. L.J. 1063, 1065-66 (2008) (patents can be used defensively to limit being subjected to infringement suits; they can also be used to create leverage in cross licensing negotiations with competitors).
\textsuperscript{19} See, e.g., Owen Thomas, \textit{As It Gears Up For War With Samsung, Apple Adds To Its Patent Pile}, BUSINESS INSIDER (Nov. 15, 2012), http://www.businessinsider.com/apple-rockstar-bidco-nortel-patents-2012-11 (last visited Nov. 16, 2012) (Apple buys 1,024 patents and patent applications to bolster its position against competitors in the mobile device market). Although many patents have little or no commercial value and hence create minimal market power continued \ldots
Non-practicing entities utilize patents to wring licensing revenue from technology producers. All of these activities are facilitated by broad patent claims that maximize the scope of patent protection. Hence, patents often include at least some claims that attempt to push the limits of what is protectable subject matter in order to maximize the potential economic value of the patent. It is these claims that tend to raise patent-eligible subject matter issues.

This article will examine the scope of patent-eligible subject matter defined by Patent Law section 101. It will look at both the legislative history and judicial interpretation of the statute, including exceptions or limitations judicially engrafted into the statute by the Supreme Court. Additionally, the competing policy concerns underlying the statute, which have been enunciated by the Court, will be examined. It will be argued that this statute should be analyzed, interpreted, and applied consistently with the usual rules generally applied by courts. This requires understanding that underlying policies are often inconsistent or competing. Such policies must therefore be balanced in crafting an applicable rule. Any resulting rule will be imperfect because it will potentially be over or under inclusive. Additionally, it will have disproportionate effects on different industries. Nevertheless, the importance of a uniform and predictable


20 See Graham & Sichelman, supra note 18, at 1064-65. See generally LANDERS, supra note 11, at §1.06, 15-17 (overview of how patents are utilized by business enterprises).

21 Patents generally contain multiple claims that vary from being very broad to being very narrow. Each claim stands on its own, so narrow and intermediate claims may be valid even if a broad claim is found invalid. This provides an incentive to include at least some very broad claims to maximize patent coverage. See MARTIN ADELMAN, RANDALL RADER, JOHN THOMAS & HAROLD WEGNER, CASES AND MATERIALS ON PATENT LAW 533 (2d ed. 2003).

22 See, e.g., Andrew Beckerman-Rodau, The Problem with Intellectual Property Rights: Subject Matter Expansion, 13 YALE J.L. & TECH. 35, 59-60 (2010) (discussion of U.S. Patent No. 4,940,658, which contains thirty-four claims covering a medical diagnostic test; noting that one claim with an extremely broad scope was the subject of litigation which ended up in the Supreme Court).

rule outweighs these deficiencies. The article will conclude with a set
of suggested rules gleaned from Supreme Court decisions that can be
used to provide more predictable results with regard to determining if
a patent claim covers patent-eligible subject matter.

II. THE CONTROLLING STATUTE—SECTION 101

Patent Law section 101 states that “[w]hoever invents or discovers
any new and useful process, machine, manufacture, or composition of
matter, or any new and useful improvement thereof, may obtain a
patent therefor, subject to the conditions and requirements of this
title.” 24 This statute can be dissected into several requirements. The
first portion of the statute, which states, “[w]hoever invents or
discovers,” arguably indicates that only an actual inventor can obtain a
patent. 25 The reference to “new” is a basic requirement of patent law
typically referred to as the novelty requirement, 26 which is dealt with
in more detail by another section of the patent law. 27 The word
“useful” has been held to be the basis for the utility requirement,
which mandates that an invention must have some use or utility to be
eligible for patent protection. 28 Finally, the statute lists several
categories—“process, machine, manufacture, or composition of
matter”—that an invention must fall within to be patent-eligible
subject matter. 29 Whether an invention falls within one of these
statutory categories has been subject to substantial judicial review. 30

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24 Id.
25 This is traditionally referred to as the derivation requirement. See J. Thomas
26 See id. at 406; Black’s Law Dictionary 1092 (7th ed. 1999).
28 See McCarthy, supra note 25, at 650-53 (“To be patentable, an invention
must have ‘utility’ in the sense that it can operate to perform some ‘useful’ function
for society.”); see also Janice Mueller, Patent Law 235 (3d ed. 2009) (“[A]
useful invention is one that possesses utility.”).
29 These categories are interchangeably referred to as defining “patentable
subject matter,” “patent eligible subject matter” or “statutory subject matter.” See
generally William T. Goglia, Annotation, Supreme Court’s Views as to What is
Patentable Subject Matter Under Federal Law as “Process,” “Machine,”
“Manufacture,” or “Composition of Matter”, 65 L. Ed. 2d 1197 (2012).
30 More specifically, very little controversy has existed over whether an
invention is a machine, manufacture, or composition of matter. See Robert
Most of the controversy has addressed the meaning of process. See id. See
Generally Goglia, supra note 29, at 1201 (“Of the terms process, machine,
manufacture, and composition of matter, the term "process" has been defined by the
court more often than the others.”).
Interpreting the meaning of these statutory categories requires a multi-step process. First, the language of the statute must be examined to determine its plain meaning. This includes ascertaining if the statute provides specific definitions of relevant terms. Second, in the absence of any definition, or if the meaning of the statute is unclear or ambiguous, the underlying purpose of the statute must be ascertained and utilized to understand the legislative intent of the statute.

Patent Law section 101 provides a definition of the term “process” which states that “[t]he term ‘process’ means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.” This definition can be broken down into two parts. The first part tells us that the terms process, art and method are essentially interchangeable. The second part of the statute, which follows the word “includes,” merely lists several examples of acceptable processes. Arguably, this second part is merely illustrative and not limiting in light of the ordinary meaning of the term “includes” in a statute. Therefore, a process can be viewed

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31 See Conn. Nat’l Bank v. Germain, 503 U.S. 249, 253 (1992) (“[The] canons of construction are no more than rules of thumb that help courts determine the meaning of legislation, and in interpreting a statute a court should always turn first to one . . . .”).
32 See id. at 253-54 (“We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there.”). In Bilski v. Kappos, 130 S. Ct. 3218, 3226 (2010), the Supreme Court stated that a statute should be given its ordinary meaning in a case involving whether an invention was within the statutory categories under Patent Law section 101. Therefore, the wording of section 101 should be given its ordinary and common meaning, unless otherwise defined, and this may be based on a dictionary definition. Id.
33 See Bilski, 130 S. Ct. at 3226. (In a decision involving the meaning of “process” in section 101 the Court states, “[w]hen a statute includes an explicit definition, we must follow that definition” (quoting Burgess v. United States, 553 U.S. 124, 130, (2008))). See generally Perrin v. U.S., 444 U.S. 37, 42 (1979) (“A fundamental canon of statutory construction is that, unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning.”).
34 See United States v. Dickerson, 310 U.S. 554, 562 (1940) (“The meaning to be ascribed to an Act of Congress can only be derived from a considered weighing of every relevant aid to construction.”).
35 35 U.S.C. § 100(b) (2006). See Bilski, 130 S. Ct. at 3237 (Stevens, J., concurring) (“[T]he Patent Act does not on its face give much guidance about what constitutes a patentable process . . . [T]he definition is not especially helpful, given that it also uses the term ‘process’ and is therefore somewhat circular.”).
36 See, e.g., 17 U.S.C. § 101 (2006) (definitional section of copyright law states that “[t]he terms ‘including’ and ‘such as’ are illustrative and not limitative”); see also BLACK’S LAW DICTIONARY 766 (7th ed. 1999) (definition of “include”).
as a method of accomplishing some result via a series of steps.\textsuperscript{37} Typically, a process claim in a patent recites a list of related actions in gerund form.\textsuperscript{38}

The patent law fails to contain any definitions of the other categories of patent-eligible subject matter. Therefore, these categories should be interpreted by using the ordinary or commonly understood meaning of the statutory language at issue.\textsuperscript{39} Absent a

\begin{quote}
A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing. . . . The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence.
\end{quote}

Later Supreme Court decisions rejected limitations on what could be considered a patent-eligible process. See, e.g., Expanded Metal Co. v. Bradford, 214 U.S. 366, 381-84 (1909) (processes not limited to chemical actions but can include purely mechanical processes). Finally, in \textit{Bilski v. Kappos}, 130 S. Ct. 3218, 3225-27 (2010), the Supreme Court rejected the conclusion of the Federal Circuit that a patent-eligible process must satisfy the so-called machine-or-transformation test which states that a claimed process is patent eligible “only if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.” Additionally, the Court specifically held that its prior decision in \textit{Cochrane} did not limit the meaning of process, \textit{id} at 3226.

\textsuperscript{38} For example, the following process claim is claim 5 in U.S. Patent No. 8,301,514 (issued Oct. 30, 2012):

\begin{quote}
A method of generating item recommendations, the method comprising: by a computer system comprising computer hardware: \textit{accessing} a transaction phrase index comprising a plurality of transaction phrases mapped to items purchased using the transaction phrases; \textit{identifying} a transaction phrase created by a target user; \textit{identifying} candidate recommendations from the transaction phrase index based at least partly on the identified target user transaction phrase, the candidate recommendations comprising one or more of the purchased items contained in the transaction phrase index; and \textit{selecting} one or more of the candidate recommendations to present to the target user as item recommendations.
\end{quote}

\textsuperscript{39} \textit{See Bilski}, 130 S. Ct. at 3226 (“In patent law, as in all statutory construction, ‘[u]nless otherwise defined, ‘words will be interpreted as taking their ordinary, contemporary, common meaning.’” (quoting \textit{Diamond v. Diehr}, 450 U.S. 175, 182 (1981))).
definition, a “machine” can be considered a tangible device or apparatus that uses mechanical or electrical energy to accomplish something.

A “manufacture” is typically a product that has been changed or transformed by a process. The Supreme Court, relying on the dictionary definition, has defined the term as “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.” Some commentators have noted that a rough way to distinguish a machine from a manufacture is that a machine has moving parts, unlike a manufacture.

A “composition of matter” has also been defined by the Supreme Court consistent with its common meaning to apply to “all compositions of two or more substances and ... all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.” Although compositions of matter are typically chemical compounds, an overlap may exist with manufactures.

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40 See Tilghman v. Proctor, 102 U.S. 707, 728 (1880) (“A machine is a thing. A process is an act, or a mode of acting. The one is visible to the eye, an object of perpetual observation.”); see also Burr v. Duryee, 68 U.S. 531, 570 (1863) (“A machine is a concrete thing, consisting of parts, or of certain devices and combination of devices.”). See generally Honolulu Oil Corp. v. Halliburton, 306 U.S. 550, 560 (1939) (“Machine includes apparatus”).


> every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result. But where the result or effect is produced by chemical action, by the operation or application of some element or power of nature, or of one substance to another, such modes, methods, or operations, are called processes.

42 Goglia, supra note 29, at § 6(a).


44 PAUL GOLDSTEIN & R. ANTHONY REESE, COPYRIGHT, PATENT, TRADEMARK AND RELATED STATE DOCTRINES 400 (6th ed. 2008); see also JANICE MUELLER, PATENT LAW 280 (3d ed. 2009).


46 Chakrabarty, 447 U.S. at 309 (1980) (determining that a genetically engineered microorganism was either a composition of matter or a manufacture continued ...
The above definitions are quite broad, which is consistent with the legislative intent of the patent law.\footnote{Id. (“The Committee Reports accompanying the [Patent] Act inform us that Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’.”).} In accordance with this intent, the Supreme Court has recognized that Congress intended a liberal view of patentable subject matter, and it has admonished courts to avoid reading limitations into the patent law.\footnote{Id. at 308.} Despite this warning, the Supreme Court has consistently read several exceptions into Patent Law section 101.\footnote{Id. at 309.} Statutory subject matter that is otherwise a process, machine, manufacture, or composition of matter is deemed non-patentable subject matter if it is a law of nature, physical phenomena, or abstract idea.\footnote{Chakrabarty, 447 U.S. at 309. The Supreme Court acknowledged that the exclusion of laws of nature, natural phenomena and abstract ideas was not contained in the statutory language of section 101. Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010). Nevertheless, it has long been viewed that these exceptions are implicitly contained in section 101. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012).} Sometimes the Court has referred to mental processes,\footnote{Gottschalk, 409 U.S. at 67.} abstract principles,\footnote{Parker, 437 U.S. at 589 (quoting Gottschalk, 409 U.S. at 67).} and fundamental truths\footnote{Id.} as being exceptions to patentable subject matter. An analysis of the legitimacy of these exceptions requires an identification of the underlying goals and justifications for patent law.

\section*{III. Patent Law: Underlying Goals and Justifications}

The basic goal of patent law is contained in the following section of the Constitution: “The Congress shall have power to . . . promote the progress of science and useful arts, by securing for limited times to . . . inventors the exclusive right to their . . . discoveries.”\footnote{U.S. CONST. art. I, § 8, cl. 8.} The plain meaning of this clause indicates that the purpose of enacting a law to protect inventor discoveries is to “promote the progress of science and useful arts.”\footnote{See Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 126-27 (2006) (Breyer, J., dissenting) (noting that the phrase “promote the progress of science and useful arts” states the constitutional objective of patent law).} Courts have interpreted this to mean that the main
The underlying goal of patent law is to benefit the public rather than rewarding the inventor for his or her efforts.\textsuperscript{56} Granting exclusive rights to inventors in the form of patents is the method of incentivizing creative and innovative conduct, which ultimately benefits everyone by increasing the public storehouse of knowledge.\textsuperscript{57}

These exclusive rights, which are essentially property rights,\textsuperscript{58} may allow an inventor to operate in the marketplace in a privileged position.\textsuperscript{59} The inventor may be able to avoid direct competition with

\textsuperscript{56} In \textit{Quanta Computer, Inc. v. LG Elecs., Inc.}, 553 U.S. 617, 626 (2008), the court stated that the "primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is 'to promote the progress of science and useful arts.'" This quoted language was reiterated approvingly in \textit{Bilski v. Kappos}, 130 S. Ct. 3218, 3252 n. 44 (2010) (Stevens, J., concurring). See also Edward Rothstein, \textit{Connections; Swashbuckling Anarchists Try to Take the $ Out of Cyberspace}, N.Y. TIMES, June 10, 2000, at B1 (noting that courts have generally interpreted this constitutional clause to mean that the goal of patent law is to benefit the public rather than the inventor).

\textsuperscript{57} See generally \textit{Bonito Boats v. Thunder Craft Boats}, 489 U.S. 141, 151 (1989) ("ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure."); see also \textit{Seymour v. Osborne}, 78 U.S. 516, 533-34 (1871) (patents are granted to inventors to compensate them for their "labor, toil, and expense" which results in an invention beneficial to the public). In \textit{Kewanee v. Bicron}, 416 U.S. 470, 480 (1974), the Supreme Court said that,

\[ \text{[t]he stated objective of the Constitution in granting the power to Congress to legislate in the area of intellectual property is to "promote the Progress of Science and useful Arts." The patent laws promote this progress by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development. The productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.} \]

\textit{See also} \textit{Sears, Roebuck & Co. v. Stiffel Co.}, 376 U.S. 225, 229 (1964) (noting that patents are granted to encourage inventive activities). Arguably, if the patent law failed to produce a benefit for the public it could be determined to be unconstitutional and void. Nevertheless, the Supreme Court has indicated its willingness, at least in the context of copyright law, to defer to Congress with regard to whether copyright law benefits the public. See generally \textit{Eldred v. Ashcroft}, 537 U.S. 186, 204-06 (2003). It is likely it would take a similar stance with regard to patent law because both patent and copyright laws are authorized by the same Constitutional provision. \textit{See} U.S. CONST. art. I, § 8, cl. 8.

\textsuperscript{58} 35 U.S.C. § 154(a)(1) (2006) (stating a patent grants "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process. .:.")

\textsuperscript{59} \textit{Id.}
regard to the patented invention by being the exclusive producer of the
invention. Alternatively, the inventor may allow others to make and
use the invention in return for negotiated royalty payments. Although
this insulation from normal marketplace pressure is a necessary market interference, it is important that it does not unduly reduce investment in innovative and creative activities. Therefore, the degree of interference must be adequate to incentivize the desired conduct without inhibiting others from engaging in innovative activities. Achieving this result is the balance that courts must accomplish in deciding which inventions are patent-eligible subject matter and which should be deemed ineligible.

Although no reference to such a balance is expressly contained in
the broad language of section 101, it is necessary for a court to interpret this section so that the statutory subject matter limitations are meaningful. Moreover, it can be argued that such a balance is mandated by the Constitution in order to achieve the goal of benefiting the public. If the statutory categories are too broadly construed the potential exists for patent owners to have property rights in fundamental concepts that are too expansive to be the subject of property rights. Such concepts are too valuable for anyone to own because such ownership could create economic barriers that would greatly inhibit others from engaging in creative endeavors that build

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60 See generally JANICE MUELLER, PATENT LAW 8 (3d ed. 2009) (noting patent law is limited exception to free competition).
61 See AMY LANDERS, UNDERSTANDING PATENT LAW §1.06 16 (2d ed. 2012). It should be noted that “[t]he decision to grant or deny permanent injunctive relief is an act of equitable discretion by the district court, reviewable on appeal for abuse of discretion.” eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006). Therefore, patent infringement may result in the patent owner having exclusive rights in the market if the infringer is permanently enjoined from infringing or the patent owner may get damages for past infringement and payment of a royalty for future infringement. Id. at 396 (“legal damages may well be sufficient to compensate for the infringement”).
63 Id. at 127 (noting courts must strike a balance between avoiding both overprotection and underprotection); See generally JANICE MUELLER, PATENT LAW 23-28 (3d ed. 2009) (providing cost/benefit analysis of patent law).
64 See U.S. CONST. art. I, § 8, cl. 8.
65 See generally Lab. Corp. of Am. Holdings, 548 U.S. at 126-28 (Breyer, J., dissenting) (2006) (noting that no one should own property rights in fundamental concepts such as laws of nature which are the basic tools of science).
66 See generally In re Chatfield, 545 F.2d 152, 157 (C.C.P.A. 1976) (“Some inventions, however meritorious, do not constitute patentable subject matter.”).
on, or require use of, such concepts.\textsuperscript{67} This would defeat the constitutional objective of promoting innovation.\textsuperscript{68} The exclusion of laws of nature, physical phenomena, and abstract ideas from patentable subject matter must be understood as an expression of this balance. Likewise, when courts have referred to mental processes, abstract principles, and fundamental truths as being exceptions to patentable subject matter, they are merely referring to the same balance. Often this balance is referred to by the oft-quoted black letter rule of law that ideas are not patentable but applications of ideas are patentable.\textsuperscript{69}

One way of thinking about these competing goals is to visualize a continuum as shown below in Fig. 1. At one end of the continuum is a potentially useful discovery. However, it is unknown how to implement or use the discovery such that it can produce a tangible and useful result.\textsuperscript{70} At the other end of the continuum is a fully developed and commercially viable device or method that uses the discovery to bring about a tangible and useful result.\textsuperscript{71}

\textsuperscript{67} Lab. Corp. of Am. Holdings, 548 U.S. at 127-28 (2006) (Breyer, J., dissenting) (noting that patent law seeks to avoid overprotection which would impede innovation).
\textsuperscript{68} See id. at 126-27.
\textsuperscript{69} See, e.g., Rubber-Tip Pencil Co. v. Howard, 87 U.S. 498, 507 (1874) (“An idea of itself is not patentable, but a new device by which it may be made practically useful is.”); see also GARY MYERS, PRINCIPLES OF INTELLECTUAL PROPERTY LAW ¶ 13.02 at 285 (2d ed. 2012) (“patentable subject matter does not include abstract ideas or theories, but only useful applications”). See generally Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1939) (“While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”).
\textsuperscript{70} See generally Brenner v. Manson, 383 U.S. 519 (1966) (disallowing a patent on a process, based on a lack of utility under section 101, even though the process worked because it produced a compound that had no known use at the time).
\textsuperscript{71} It should be noted that neither commercial viability nor actual construction of an invention is required to obtain a patent. See Joy v. Morgan, 295 F. 931, 935 (D.C. 1924). Filing a valid patent application that discloses enough information to enable a person of ordinary skill in the relevant art to make and use the invention is sufficient. Such disclosure is referred to as a constructive reduction to practice. See Eastman Kodak Co. v. E. I. DuPont de Nemours & Co., 298 F. Supp. 718, 725 (E.D. Tenn. 1969); see also Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986) (“constructive reduction to practice occurs when a patent application on the claimed invention is filed”).
If undeveloped discoveries and abstract ideas were viewed as potentially patentable subject matter, it would arguably incentivize a certain amount of early stage research and development activity due to the significant potential economic value of such subject matter. It could be further argued that such incentivizing might be necessary to facilitate early stage research in capital-intensive areas of technology. If such early stage discoveries are ineligible for patent protection until they are developed into commercially viable products, that increases the economic risk and this may be a disincentive to devote resources to such activities.

Nevertheless, a counterargument is that allowing early stage discoveries and abstract ideas to be patent eligible may inhibit further research and development activities by others.

The Supreme Court has repeatedly indicated that early stage discoveries and abstract ideas should be viewed as “the basic tools of scientific and technological work” that should be free for everyone to utilize in order to prevent future innovation from being inhibited.

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72 See Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1301 (2012) (granting patents to “those who discover new laws of nature and the like might well encourage their discovery”); see also Morton v. N.Y. Eye Infirmary, 2 F. Cas. 320 (S.D.N.Y. 1862) (No. 9865) (determining that the discovery that ether could be used as an anesthetic during surgery was not patentable even though its value was so great that it could not be quantified).

73 See, e.g., Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 126-27 (2006) (Breyer, J., dissenting) (incentives are relevant to early stage research which is both expensive and time consuming to conduct).

74 See, e.g., Mayo Collaborative Servs., 132 S. Ct. at 1301 (noting that “[t]he [Supreme] Court has repeatedly emphasized . . . a concern that patent law not inhibit further discovery by improperly tying up the future use of law of nature.”).


76 See, e.g., Mayo Collaborative Servs., 132 S. Ct. at 1301.
Hence, the Supreme Court has stated in multiple opinions that patent law must strike a balance between utilizing patents to incentivize innovation and avoiding granting patents that inhibit future innovation. The law’s goal is therefore to locate the optimum point on the continuum shown in Fig. 1, above, where the transition from unpatentable subject matter to patent-eligible subject matter is deemed to occur. The terms, “laws of nature,” “physical phenomena,” “abstract ideas,” “mental processes,” “abstract principles,” and “fundamental truths” have been used by the Supreme Court to identify subject matter deemed unpatentable. However, these terms can be viewed merely as conclusions that are applied to an invention after it has been deemed to fall outside the statutory categories in section 101. Although the Federal Circuit unsuccessfully attempted to adopt a specific controlling test—the machine-or-transformation test—to determine patent eligibility of processes under section 101, the Supreme Court has taken a more flexible and open-ended approach. In contrast to the Federal Circuit, the Supreme Court has held that the machine-or-transformation test can be utilized, but it made clear that the test is not controlling and that other tests could also be used.

77 See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998) (“[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time. The balance between the interest in motivating innovation and enlightenment by rewarding invention with patent protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition on the other, has been a feature of the federal patent laws since their inception.”); see also Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989) (“The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’”); Bilski, 130 S. Ct. at 3228 (“[T]he patent law faces a great challenge [today] in striking the balance between protecting inventors and not granting monopolies over procedures that others would discover by independent, creative application of general principles.”).

78 See, e.g., Lab. Corp. of Am. Holdings, 548 U.S. at 126 (Breyer, J., dissenting) (“The relevant principle of law ‘[e]xcludes from . . . patent protection . . . law of nature, natural phenomena, and abstract ideas.’”).

79 See Mark A. Lemley, Michael Risch, Ted Sichelman & R. Polk Wagner, Life after Bilski, 63 STAN. L. REV. 1315, 1317 (June 2011) (noting that the rule making abstract ideas unpatentable can be viewed as a rule against overclaiming by inventors).

80 In re Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008) (stating that under the machine or transformation test “[a] claimed process is surely patent eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”).

81 Id. at 956 (stating that an invention was not a patent-eligible process under section 101, and “the machine-or-transformation test . . . is the governing test for continued . . .
Judge Linn adroitly summed up the state of the law with regard to patent-eligible subject matter in a recent Federal Circuit decision that addressed the meaning of abstract idea. Judge Linn stated:

The abstractness of the “abstract ideas” test to patent eligibility has become a serious problem, leading to great uncertainty and to the devaluing of inventions of practical utility and economic potential . . . . In Bilski, the Supreme Court offered some guidance by observing that “[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.” (citation omitted) This court has also attempted to define “abstract ideas,” explaining that “abstract ideas constitute disembodied concepts or truths which are not ‘useful’ from a practical standpoint standing alone, i.e., they are not ‘useful’ until reduced to some practical application.” (citation omitted) More recently, this court explained that the "disqualifying characteristic" of abstractness must exhibit itself "manifestly" "to override the broad statutory categories of patent eligible subject matter." (citation omitted) Notwithstanding these well-intentioned efforts and the great volume of pages in the Federal Reporters treating the abstract ideas exception, the dividing line between inventions that are directed to patent ineligible abstract ideas and those that are not remains elusive. "Put simply, the problem is that no one understands what makes an idea 'abstract.'" (citation omitted)83

The theoretical backdrop for the question of what is and is not determining patent eligibility of a process under § 101."), cert. granted, 130 S. Ct. 3218, 3227, 3231 (2010) (upholding the conclusion of the Federal Circuit that the invention at issue was not statutory subject matter under section 101; however, noting, contrary to the Federal Circuit’s opinion, that the machine or transformation test could be utilized but that it was not the sole controlling test); see Bilski, 130 S. Ct. at 3235 (Stevens, J., concurring) (opining that although the machine-or-transformation test is not controlling it is still an effective test for evaluating the patent eligibility of most processes).

82 See Bilski, 130 S. Ct. at 3231 (“In disapproving an exclusive machine-or-transformation test, we by no means foreclose the Federal Circuit's development of other limiting criteria that further the purposes of the Patent Act and are not inconsistent with its text.”).

The patent-eligible subject matter is both clear and logical in light of the balancing between competing policies enunciated by the Supreme Court. However, application of theory to specific factual scenarios is a challenge for lower courts in the absence of clear rules or tests. Nevertheless, courts will have to apply the legal theory on a case-by-case basis in an effort to produce the most equitable decision between competing parties. A consequence of this approach will be a lack of predictability, which is problematic.

IV. The Importance of Predictability

Patent law and law in general provide a framework of rules that facilitate an orderly society. This promotes marketplace conduct oriented to competitive activities for economic gain. This can only occur if the law demonstrates a high degree of predictability, which is necessary for economic decision making and future planning.

Application of a variety of tests including the machine-or-transformation test, which are discussed below, to determine whether

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84 See generally Miami Laundry Co. v. Fla. Dry Cleaning & Laundry Bd., 182 So. 759, 763-64 (Fla. 1938) (“Laws are nothing more than rules promulgated by government as a means to an ordered society.”); Baer v. Jarzombek, 153 Misc. 2d 351, 353 (Civ. Ct. City of N.Y. 1992) (Loft law enacted as an attempt to bring order to the confusing body of law for resolving landlord tenant disputes involving lofts). See generally Zunaira Zaki, Fiscal Cliff’ Worries Add to Jobless Woes, ABC News CONSUMER REPORT (Dec. 3, 2012, 12:54pm) available at http://abcnews.go.com/blogs/business/2012/12/fiscal-cliff-worries-add-to-jobless-woes/ (noting effects of uncertainty on businesses caused by dispute between Congress and the President about how to modify the federal budget to avoid the so-called impending fiscal cliff); Hayden W. Gregory, Proving Infringement in Divided Performance Process Claims: Something’s Gotta Give, 5 LANDSLIDE vol. 2, at 1 (November/December 2012) (“The success and viability of any legal system is dependent upon its ability to provide stability and certainty while at the same time sufficient flexibility to adjust and adapt to changing conditions and needs.”).

85 See generally Ronald J. Colombo, Cooperation With Securities Fraud, 61 ALA. L. REV. 61, 117 (2009) (“Businessmen and businesswomen require clear and predictable laws in order to appropriately conduct themselves and their businesses.”); Christopher Guzelian, True and False Speech, 51 B.C. L. REV. 669, 672 (2010) (noting some commentators have asserted that it is important for law to be predictable so that consequences of one’s actions can be known in advance); Jill Fisch, The Peculiar Role of the Delaware Courts in the Competition for Corporate Charters, 68 U. CIN. L. REV. 1061, 1070 (2000) (“Commentators have observed that, with respect to business transactions, it is often more important that the applicable legal rules be settled than that they be settled correctly.”). See generally Bilski, 130 S. Ct. at 3231 (Stevens, J., concurring) (“In the area of patents, it is especially important that the law remain stable and clear.”).

86 In Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010), the Court seemed to be giving the Federal Circuit express permission to develop new tests to be used in continued...
a particular innovation is statutory subject matter under section 101 has the advantage of some degree of predictability.\textsuperscript{87} Certainly it will produce a more predictable result than the Supreme Court’s open-ended approach. In light of the many years that courts have struggled with this issue, the Court’s open-ended approach can arguably be viewed as a quest to find the perfect test. Unfortunately, it is an imperfect world, so a quest for the perfect test amounts to an attempt to attain the unattainable. In light of this, the machine-or-transformation test and the additional suggested tests discussed below, although imperfect, may represent the best possible approach for providing some degree of certainty or predictability.

Arguably, use of the machine-or-transformation test and the other tests suggested below may cause certain problems. First, the tests have the potential to draw somewhat arbitrary lines, which might result in some inventions that should be deemed patent-eligible subject matter being found to be outside the domain of statutory subject matter. Alternatively, some inventions that are not patent eligible may be found eligible. Second, it may have a disproportionate effect on some industries that rely more on patent protection than other industries.\textsuperscript{88} Finally, it may lead to unreasonable or unfair results under certain circumstances. None of these concerns are limited to statutory subject matter issues. These concerns arise in many areas of the law including under other provisions of the patent law.

For example, an invention that is deemed statutory subject matter must also be found to be new or novel to be patentable.\textsuperscript{89} One requirement of novelty is that no printed publications publicly available anywhere in the world disclose that a third party previously invented the same invention.\textsuperscript{90} Courts have applied a somewhat rigid conjunction with, or in lieu of, the machine-or-transformation test when it stated “[i]n disapproving an exclusive machine-or-transformation test, we by no means foreclose the Federal Circuit’s development of other limiting criteria that further the purposes of the Patent Act and are not inconsistent with its text.”

\textsuperscript{87} See generally In re Chatfield, 545 F.2d 152, 161 (C.C.P.A. 1976) (Rich, J., dissenting) (noting at a time when patent eligibility of software was unsettled that having settled law on this was an important socioeconomic issue of great magnitude).

\textsuperscript{88} For example, in Herbert Hovenkamp, Empire: Innovation and the Domain of Competition Policy, 60 ALA. L. REV. 103, 124-25 (2008), the author notes that the pharmaceutical industry favors strong patents; but the high tech industry, which is largely made up of software companies, favors weak patents. See generally Robert Mazzoleni & Richard Nelson, The Benefits and Costs of Strong Patent Protection, 27 RESEARCH POLICY 273, 281 (1998) (noting differing economic effect of patent law on different areas of technology).


\textsuperscript{90} Previously, Patent Law section 35 U.S.C. § 102(a) (2006) provided that an
test, which can result in unfair results, at least from a reasonableness perspective. Typically, a public accessibility standard applies today. For example, under this test most documents that are properly indexed in a paper card catalogue at the library or in a modern computerized catalogue are considered prior art if they could be reasonably discovered by searching the paper or electronic catalogues. This applies despite the fact that it is unreasonable to expect an inventor to search every library catalogue for relevant printed publications. An obscure publication that few people are aware exists could potentially bar an inventor from obtaining a patent on an invention he or she spent substantial time, effort, and money developing. Likewise, such an obscure reference may never be discovered and a patent may be issued to a person who is not in fact the first inventor. Applying a reasonableness standard such that only printed publications that an inventor could reasonably be expected to find would produce a fairer result. However, such a reasonableness standard would produce uncertainty. One might explain rejection of such a standard as an effort to inject predictability into the process of determining novelty. Alternatively, this strict standard can be viewed as a balance between granting an inventor a patent on his or her innovation and the importance of preventing public domain subject matter from being removed from the public domain by issuance of a patent for a previously known invention. Strict judicial application of this rule suggests courts strongly favor protecting the public storehouse of knowledge from being diminished.

Novelty can also be negated by public use of an invention.

invention “described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent” prevents the applicant from obtaining a patent. Effective March 16, 2013, this section was renamed 35 U.S.C. § 102(a)(1) (Supp. V 2012) and it provides that an invention “described in a printed publication before the effective filing date of the claimed invention” prevents the applicant from obtaining a patent. The previous law will continue to be applicable to patent applications filed prior to March 16, 2013 and the new law will be applicable to patent applications filed on or after March 16, 2013.

91 In re Hall, 781 F.2d 897, 898-99 (Fed. Cir. 1986); see also In re Klopfenstein, 380 F.3d 1345, 1347, 52 (Fed. Cir. 2004) (slide presentation of 14 slides which were printed and pasted onto poster boards, and made accessible to the public for several days was held to be a printed publication).

92 See AMY LANDERS, UNDERSTANDING PATENT LAW §14.02[B][2], at 188 (2d ed. 2012) (publicly accessible printed publications are in the public domain and therefore they cannot removed from the public domain and made private property via granting a patent).

93 Previously, under 35 U.S.C. § 102(b) (2006), an invention was not patentable if “the invention was . . . in public use . . . more than one year prior to the date of the application for patent in the United States . . . .” Effective March 16, 2013, recodified as 35 U.S.C. § 102(a)(1) (Supp. V 2012), an invention will not be

continued . . .
Courts have strictly interpreted public use such that it is triggered when an inventor reveals his invention to a single person who never discloses or tells anyone else about the invention. Placing an invention on sale may also destroy novelty. A single prior sale of an invention satisfies the on-sale bar. Again, it can be argued that the above results strongly favor predictability even if the result may be viewed as unreasonable or unfair in some circumstances.

The goal of predictability, even if it trumps reasonableness or fairness in some situations, is not limited to patent law. Assume, for example, that Amy leaves her watch at a store that both fixes watches and sells used watches. Inadvertently, her watch is sold to Bob who entered the store looking to buy a used watch. At common law, Amy’s ownership rights would enable her to recover the watch from Bob. However, under Article Two of the Uniform Commercial Code, adopted by most states, Bob would typically become the owner of the watch, and Amy’s only recourse would be a suit for damages against the store. This result is unfair because it improperly deprives Amy of her property, and it places the burden of

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94 See Egbert v. Lippmann, 104 U.S. 333, 336 (1881); see also Watson v. Allen, 254 F.2d 342, 345 (D.C.C. 1958) (“[P]ublic use exists where the invention is used by, or exposed to, anyone other than the inventor or persons under an obligation of secrecy to the inventor.”).

95 Previously, under 35 U.S.C. § 102(b) (2006), an invention was not patentable if “the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States . . . .” Effective March 16, 2013, recodified as 35 U.S.C. § 102(a)(1) (Supp. V 2012), an invention will not be patentable if the invention was “on sale . . . before the effective filing date of the claimed invention . . . .” The previous law will continue to be applicable to applications filed prior to March 16, 2013, and applications filed on or after March 16, 2013 will be governed by § 102(a)(1) (Supp. V 2012).

96 Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 67-68 (1998) (applying the on-sale bar to an invention subject to a commercial offer of sale when it was ready for patenting).


99 See U.C.C. § 2-403(2) (2003); see generally BOYER, supra note 97 (explaining how U.C.C. § 2-403 alters the common law by allowing a buyer, under certain circumstances, to acquire a better title than seller had to sell).

100 See U.C.C. § 2-403(2) (2003).
bringing legal action for compensation on her. 101 Nevertheless, this allows a shopper purchasing goods in good faith and in the ordinary course of business to assume the store has ownership of the goods it is selling. 102 This eliminates placing the burden on shoppers to verify ownership of goods purchased in commonplace retail transactions, which would make such transactions cumbersome and consequently more costly. 103 This bright-line or predictable rule codified in the Uniform Commercial Code favors societal interests over an individual’s property rights. 104

Recording statutes in many states likewise enable a non-owner to deprive a true owner of rights in real estate under certain circumstances. 105 For example, in a jurisdiction that has a notice recording statute in effect, a bona fide purchaser of real estate from a non-owner of the real estate may have superior rights to the true owner if the true owner failed to record his or her ownership rights. 106 This is true even though such recording is generally not required. 107

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101 See generally Deweldon, Ltd. v. McKean, 125 F.3d 24, 28 (1st Cir. 1997) (“It shifts the risk of resale to the one who leaves his property with the merchant.”).

102 See id. at 27 (explaining section 2-403(2) “is designed to enhance the reliability of commercial sales by merchants who deal in the kind of goods sold”). See also Patricia Youngblood Reyhan, A Chaotic Palette: Conflict of Laws in Litigation Between Original Owners and Good-Faith Purchasers of Stolen Art, 50 Duke L.J. 955, 973-76 (2001).

103 See Johnson & Johnson Prods., Inc. v. Dal Int’l Trading Co., 798 F.2d 100, 104 (3rd Cir. 1986) (“The purpose of the good faith purchaser doctrine [codified in U.C.C. section 2-403] . . . is to promote commerce by reducing transaction costs; it allows people safely to engage in the purchase and sale of goods without conducting a costly investigation of the conduct and rights of all previous possessors in the chain of distribution.”).

104 See generally BOYER, supra note 97 (noting that U.C.C. section 2-403 represents “a valued judgment that security of transactions under [certain] circumstances . . . was more important than the protection of the innocent owner”).

105 See generally JESSE DUKEMINIER, JAMES E. KRIER, GREGORY S. ALEXANDER & MICHAEL H. SCHILL, PROPERTY 646-47 (7th ed. 2010) (explaining that at common law, the first-in-time buyer owns real estate even if he or she does not record the deed, but a subsequent bona fide purchaser may have superior rights to the buyer under an applicable recording statute).

106 “[T]he term ‘bona fide purchaser’ . . . is generally understood to mean ‘[o]ne who has purchased property for value without notice of any defects in the title of the seller.’” U.S. v. Watkins, 320 F.3d 1279, 1283 (11th Cir. 2003) (quoting In re Walter, 45 F.3d 1023, 1030 (6th Cir. 1995)). See generally WILLIAM B. STOEBUCK & DALE A. WHITMAN, THE LAW OF PROPERTY § 11.10, at 882-89 (3d ed. 2000) (discussing the different types of notice, which can include actual, constructive, or inquiry notice).

107 JOSEPH WILLIAM SINGER, PROPERTY § 11.4.5.2, at 538 (3d ed. 2010).

108 See id. § 11.4.5.1, at 538 (explaining that recording of deed is not required for property transfer to be valid in almost all states).
similar result occurs for a transfer of ownership rights in a patent in light of the recording statute contained in the patent law.\textsuperscript{109} Analogous to the rationale for section 2-403, discussed above, the bona fide purchaser rules for real estate and for patents insure the existence of vibrant markets by enabling buyers to have confidence they own the property purchased free of prior claims.\textsuperscript{110}

The concept of constructive notice\textsuperscript{111} also creates a predictable rule with regard to whether a person has knowledge of many publicly available documents such as land transfers, corporate records, liens, financing statements recorded pursuant to Uniform Commercial Code Article 9,\textsuperscript{112} federal trademark registrations,\textsuperscript{113} issued patents,\textsuperscript{114} and many other public records.\textsuperscript{115} Under this concept a person is held to have notice of all of these documents without regard to whether he or she actually has such notice.\textsuperscript{116} This may be unfair in some situations, but it promotes certainty and predictability by encouraging and enabling interested parties to rely on the validity of such documents, which facilitates transactions by reducing transactions costs.

The common law tort doctrine of vicarious liability shifts tort liability to an employer under certain circumstances.\textsuperscript{117} Generally, it

\textsuperscript{109} 35 U.S.C. § 261 (2006) (“An assignment, grant or conveyance shall be void as against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it is recorded in the Patent and Trademark Office within three months from its date or prior to the date of such subsequent purchase or mortgage.”). See generally Filmtec Corp. v. Allied-Signal Inc., 939 F.2d 1568, 1573-74 (Fed. Cir. 1991) (noting that section 261 utilizes the same underlying concept as a state real property recording statute).


\textsuperscript{111} Schoedel v. State Bank of Newburg, 13 N.W.2d 534, 535 (Wis. 1944) (“[C]onstructive notice is in point of literal fact neither notice nor knowledge. For the promotion of sound policy or purpose, the legal rights and interests of parties are treated as though they had actual notice and knowledge.”).


\textsuperscript{114} 35 U.S.C. § 287(a) (2006) (explaining that affixing the word “patent” or “pat” along with the patent number puts the public on notice of the patent).

\textsuperscript{115} See BLACK’S LAW DICTIONARY 1088 (7th ed. 1999).

\textsuperscript{116} See generally Schoedel v. State Bank of Newburg, 13 N.W.2d 534, 535 (Wis. 1944) (explaining that constructive notice is a legal fiction which ascribes notice to someone without regard to whether he or she has actual notice).

\textsuperscript{117} Alan Q. Sykes, The Boundaries of Vicarious Liability: An Economic Analysis of the Scope of Employment Rule and Related Legal Doctrines, 101 HARV. L. REV. continued...
renders an employer liable for negligent conduct of an employee when the employee negligently injures a third party in the course of employment. This rule applies without regard to any culpability on the part of the employer. Likewise, banks are typically liable for forged checks and fraudulent use of credit cards by a third party via statute, without regard to whether the bank has any culpability.

In each of these cases, the law makes a policy-based risk allocation between the bank and an innocent customer. Although such non-culpability-based risk allocation in the above examples is arguably unfair, it allows a business enterprise to plan accordingly for risk by setting aside funds or purchasing insurance. Such a predictable result is preferable to having an unknown, non-quantifiable monetary risk for which it is difficult to plan.

In contrast to promoting predictability, in some situations the law favors a reasonable result when insuring a fair or equitable outcome is more important than achieving predictability. Generally, this approach is heavily fact-based and applies on a case-by-case basis rather than broadly to a class of relationships or transactions, minimizing any potential externalities. For example, a valid and binding contract requires the existence of consideration. Nevertheless, under the doctrine of promissory estoppel, a contract lacking consideration may be enforced against a party who engaged in certain actions that lead another reasonable person to rely on such actions to his or her detriment. Similar estoppel doctrines exist in other areas of law


119 See Carter v. Reynolds, 815 A.2d 460, 463 (N.J. 2003) (“Although as a general rule of tort law, liability must be based on personal fault, the doctrine of respondeat superior recognizes a vicarious liability principle pursuant to which a master will be held liable in certain cases for the wrongful acts of his servants or employees.”).


121 See Lost or Stolen Credit, ATM, and Debit Cards, FED. TRADE COMM’N, http://www.ftc.gov/bcp/edu/pubs/consumer/credit/cre04.shtm (last visited Mar. 24, 2013) (“Your maximum liability under federal law for unauthorized use of your credit card is $50.”).


such as easement by estoppel, agency by estoppel, and corporation by estoppel.

In the context of patent infringement, some aspects of a literal infringement analysis are applied in a somewhat mechanical or predictable fashion. For example, a finding of literal infringement of a typical claim requires that every limitation contained in the claim must exist in the infringing device or method. Consider the following patent claim:

1. A sealed crustless sandwich, comprising:
   a first bread layer having a first perimeter surface coplanar to a contact surface;


126 An easement is a real property interest, which means it is subject to the statute of frauds and therefore requires a written document to be created. See GERALD KORN GOLD, PRIVATE LAND USE ARRANGEMENTS: EASEMENTS, REAL COVENANTS AND EQUITABLE SERVITUDES § 3.04(a), at 33 (2d ed. 2004). A license is a personal right that is freely revocable. Id. § 3.05(c), at 39. However, a licensee who improves the property by building a road and house on it, relying on the license to his or her detriment, may be able to assert an estoppel argument to bar the license from being revoked. The result is essentially the equivalent of an easement that arises from estoppel in lieu of a writing. See id. § 3.05, at 36-39; Holbrook v. Taylor, 532 S.W.2d 763 (Ky. 1976).

127 Agency by estoppel is an equitable theory under which someone who is not an agent can be held to be an agent of a person who holds out that individual as such, thereby inducing a third party’s reliance. Battle v. Seibels Bruce Ins. Co., 288 F.3d 596, 603 (4th Cir. 2002).

128 In Harry Rich Corp. v. Feinberg, 518 So. 2d 377, 379 (Fla. Dist. Ct. App. 1987), the court stated that
   The long-standing rule that an association, until it comes into existence as a corporation, cannot be bound by acts done or promises made in its behalf and cannot therefore be subject to the entry of a judgment against it . . . would produce harsh results if applied without resort to equitable doctrines. One such doctrine is ‘corporation by estoppel,’ under which private litigants are estopped to assert the nonexistence of the corporation if they have by their conduct or words affirmed or relied on its existence.
   See also Cranson v. I.B.M., 200 A.2d 33 (Md. 1964) (holding that the creditor of corporation was estopped from asserting that the corporation did not exist when contract with corporation was signed, in light of the fact that the creditor erroneously dealt with the debtor as if it were a corporation at the time the contract was signed).

at least one filling of an edible food juxtaposed to said
contact surface;
a second bread layer juxtaposed to said at least one
filling opposite of said first bread layer, wherein said
second bread layer includes a second perimeter surface
similar to said first perimeter surface;
a crimped edge directly between said first perimeter
surface and said second perimeter surface for
sealing said at least one filling between said first bread layer
and said second bread layer;
wherein a crust portion of said first bread layer and said
second bread layer has been removed.\textsuperscript{130}

If every aspect of the above claim is copied except that the crust is
not removed from the bread, the claim is not literally infringed
because one limitation contained in the claim—removing the crust
from the bread—was omitted.\textsuperscript{131}

The following claim describes a system for tracking clothing in a
dry cleaning business. Assume every aspect of the claim is copied
except that a laser printer is used in lieu of a dot matrix printer.
Paragraph three of the claim specifically limits the system to using a
dot matrix printer so using a laser printer avoids a finding of literal
infringement.

1. The inventory control and reporting system, comprising:
   a data input device for manual operation by an
   attendant, the input device having switch means
   operable to encode information relating to sequential
   transactions, each of the transactions having articles
   associated therewith, said information including
   transaction identity and descriptions of each of said
   articles associated with the transactions;
   a data processor including memory operable to
   record said information and means to maintain an
   inventory total, said data processor having means to
   associate sequential transactions with unique sequential
   indicia and to generate at least one report of said total
   and said transactions, the unique sequential indicia and

\textsuperscript{130} U.S. Patent No. 6,004,596 (filed Dec. 08, 1997) (issued Dec. 21, 1999).
\textsuperscript{131} See London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1539 (Fed. Cir.
1991) (“There can be no infringement as a matter of law if a claim limitation is
totally missing from the accused device.”) (citation omitted). See also NARD, supra
note 129, at 456.
the descriptions of articles in the sequential transactions being reconcilable against one another;

a dot matrix printer operable under control of the data processor to generate a written record of the indicia associated with sequential transactions, the written record including optically-detectable bar codes having a series of contrasting spaced bands, the bar codes being printed only in coincidence with each said transaction and at least part of the written record bearing a portion to be attached to said articles; and,

at least one optical scanner connected to the data processor and operable to detect said bar codes on all articles passing a predetermined station, whereby said system can detect and localize spurious additions to inventory as well as spurious deletions therefrom.\textsuperscript{132}

Nevertheless, the Supreme Court created an equitable doctrine called the doctrine of equivalents,\textsuperscript{133} which allows, under certain circumstances, a determination that an accused device is infringing even though it is literally not covered by a claim.\textsuperscript{134} This doctrine, which lacks any statutory support under the patent law\textsuperscript{135} and conflicts with the notice function of claims,\textsuperscript{136} has been justified by the Court in order to insure that patent claims are not interpreted so narrowly that a disincentive exists to file patents.\textsuperscript{137}

Such a consequence would be inimical to the public interest.

\textsuperscript{132} This claim was involved in an appeal in Markman v. Westview Instruments, Inc., 52 F.3d 967, 972 (Fed. Cir. 1995), aff’d, 517 U.S. 370 (1996).
\textsuperscript{133} See Mueller, supra note 28, at 351 (noting the “doctrine of equivalents is entirely judge-made law”).
\textsuperscript{134} See Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997) (“Under this doctrine [of equivalents], a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is ‘equivalence’ between the elements of the accused product or process and the claimed elements of the patented invention.”). See also Landers, supra note 11, § 29.08, at 385.
\textsuperscript{135} See Mueller, supra note 28, at 351 (stating “the doctrine of equivalents is entirely judge-made law”).
\textsuperscript{136} Warner-Jenkinson Co., 520 U.S. at 29 (noting conflict between notice function of claims and the doctrine of equivalents). See also Mueller, supra note 28, at 353 (noting tension between notice of equivalents and notice function of patent claims).
Under this doctrine, a court might find the above claim infringed if a laser printer was used in lieu of a dot matrix printer even if the laser printer was not invented until after the patent containing the above claim was granted. The important question to address with regard to statutory subject matter under Patent Law section 101 is whether a predictable rule or an equitable rule should be applied.

V. PREDICTABILITY AND STATUTORY SUBJECT MATTER

The importance of predictability in patent law jurisprudence is clear. Patents are typically commercial documents that affect the viability of business enterprises in diverse ways. This can include raising capital, prioritizing research, and developing budgets and general business planning. The flexible or open-ended approach adopted by the Supreme Court with regard to determining what is or is not statutory subject matter negatively impacts predictability. Both the Federal Circuit and commentators have noted that lack of predictability produces uncertainty that is problematic. Nevertheless, adoption of predictable or bright-line rules may create some unintended issues. Such rules may over- or under-include appropriate subject matter; they might produce unfair results in certain situations and they may have disparate effects on different industries. However, on balance, the benefits of predictability outweigh these

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138 Literal infringement is evaluated at the time a patent application was filed. Infringement under the doctrine of equivalents is determined at the time of infringement. Therefore, technology that exists at the time of infringement can be an equivalent element or limitation under the doctrine even if it did not exist at the time of filing. NARD, supra note 129, at 476-78.

139 See generally Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010) (Stevens, J., concurring) (“In the area of patents, it is especially important that the law remain stable and clear.”).

140 See generally LANDERS, supra note 11, § 1.06, at 15-16 (2d ed. 2012) (discussing how patent owners use patents).


142 Donald S. Chisum, Weeds and Seeds in the Supreme Court’s Business Method Patents Decision: New Directions for Regulating Patent Scope, 15 LEWIS & CLARK L. REV. 11, 14 (2011) (explaining that current statutory subject matter law can lead to arbitrary and unpredictable results, which can cause uncertainty that “does substantial harm to the effective operation of the patent system”); See Lemley, supra note 79, at 1316 (noting that “the problem is that no one understands what makes an idea ‘abstract,’ and hence ineligible for patent protection”).
potential negative effects for a variety of reasons. First, only a small number of patent disputes have historically involved statutory subject matter under section 101. It is typically not an issue with regard to product claims. Today, the issue seems to arise most commonly in a limited number of disputes involving method claims for medical diagnostic tests and for methods of doing business. And, even in cases where it does arise, the invention at issue will often be denied patent protection based on obviousness, lack of novelty, or failure to satisfy various disclosure requirements. In light of this, the Federal Circuit has stated:

District courts have great discretion to control the conduct of proceedings before them, including the order of presentation of issues and evidence and the sequence of events proscribed by the Federal Rules and leading up to judgment. See, e.g., Amado v. Microsoft Corp., 517 F.3d 1353, 1358 (Fed. Cir. 2008) ("District courts . . . are afforded broad discretion to control and manage their dockets, including the authority to decide the order in which they hear and decide issues pending before them."). Although § 101 has been characterized as a “threshold test,” (citation omitted) [by the Supreme Court], and certainly can be addressed before other matters touching the validity of patents, it need not

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143 See generally NARD, supra note 129, at 476-78 (stating the statutory subject matter requirement has not historically been a major impediment to obtaining patent protection).
144 Nevertheless, in In re Nuijten, 500 F.3d 1346, 1348 (Fed. Cir. 2007), the court found a claim to an electronic signal, which was arguably a product claim, was not patent-eligible subject matter under section 101.
146 See, e.g., Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010) (discussing a method of hedging financial risk in the commodities market); CLS Bank Int'l, 685 F.3d at 1343 (discussing method and product claims for a trading platform that minimizes settlement risk when exchanging financial obligations); In re Comisky, 554 F.3d 967, 970 (Fed. Cir. 2009) (discussing method and product claims for an arbitration system).
always be addressed first, particularly when other sections might be discerned by the trial judge as having the promise to resolve a dispute more expeditiously or with more clarity and predictability. (citation omitted) Thus, consistent with its role as the master of its own docket, a district court properly acts within its discretion in deciding when to address the diverse statutory challenges to validity. 147

Therefore, in some disputes it may be advisable for a court to initially evaluate a patent or patent application under Patent Law sections 102, 103, and 112. Only if the invention passes muster under these sections should a statutory subject matter analysis be undertaken. This would minimize the instances of invoking section 101 because it would typically only be relevant in the limited number of cases where the discovery at issue is novel, nonobvious, and has utility in addition to satisfying the enablement, written description, and definiteness requirements.

This approach is not unique to patent law. It is commonplace for courts to avoid a difficult issue if a dispute can be resolved by resorting to an alternate issue. 156 Such avoidance is often appropriate

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147 CLS Bank Int'l, 685 F.3d at 1348. See generally Bilski, 130 S. Ct. at 3225 (explaining that to be patentable an invention must be patent eligible under section 101 in addition to satisfying Patent Law sections 102, 103 and 112).


153 The enablement requirement, which is contained in 35 U.S.C. § 112(a), is satisfied if the patent discloses sufficient information so that a person of ordinary skill in the relevant technology can make and use the invention without having to engage in undue experimentation. See MagSil Corp. v. Hitachi Global Storage Techs., 687 F.3d 1377, 1380 (Fed. Cir. 2012).

154 The written description requirement, which is contained in 35 U.S.C. § 112(a), is satisfied if the patent discloses sufficient information to show that the inventor was in possession of the claimed invention at the time the patent application was initially filed. See Crown Packaging Tech., Inc. v. Ball Metal Bev. Container Corp., 635 F.3d 1373, 1380 (Fed. Cir. 2011).

155 Section 112 states that the patent shall include “one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.” 35 U.S.C. § 112(b) (2006). This is commonly referred to as the definiteness requirement. See NovelPoint Learning LLC v. Leapfrog Enters., Inc., No. 6:10-cv-229 JDL, 2012 U.S. Dist. LEXIS 24701, at *6-7 (E.D. Tex. 2012). See also Noah Sys. Inc. v. Intuit Inc., 675 F.3d 1302, 1311 (Fed. Cir. 2012).

in order to avoid creating precedent that may create unintended consequences.

Second, over- or under-inclusion is a common issue whenever a bright-line rule is utilized in the context of balancing competing policies. Over time, if certain systemic issues continuously arise, courts can develop additional rules to resolve these problems. This is the typical way the law develops because it is impossible to foresee the unique situations and technological advances that will arise in the future. And, if those unique situations or advances become commonplace the rule can be modified, adapted, or changed in the future as appropriate.

Examination of the creation and development of the judicial doctrine of equivalents infringement provides a case study for how the law can develop.157 Initially, the Supreme Court was concerned about creating a disincentive to file patent applications if patent claims were construed too narrowly because the consequence would be a reduction in the public storehouse of knowledge gained from patent disclosures.158 In contrast, the Court understood that patent claims serve a notice function by delineating between what is protected and what is in the public domain.159 This notice is enhanced by applying a literal infringement analysis. The Court balanced these two competing policies by creating the judicial doctrine of equivalents, which allows a patent owner, under certain circumstances, to prevail in a patent infringement action even though literal infringement is demonstrably

property dispute under an adverse possession theory so the court did not need to decide the validity of a tax deed); Van Sandt v. Royster, 83 P.2d 698, 703 (Kan. 1938) (stating it was unnecessary to address prescription issue because case resolved based on finding creation of an easement by implication). See generally Cummings v. Conglobal Indus., No. 07-CV-409-TCK-SAJ, 2008 U.S. Dist. LEXIS 81967, at *7-8 (N.D. Okla. 2008) (explaining that federal courts should avoid deciding constitutional law issues if alternate grounds exist to resolve the dispute).

157 Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607-09 (1950) (explaining that infringement can be asserted even if there is no literal infringement when the allegedly infringing device “performs substantially the same function [as the patented invention] in substantially the same way to obtain the same result”). See also Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997) (citing Graver Tank & Mfg. Co. and reaffirming the validity of the doctrine of equivalents).

158 See Graver Tank & Mfg. Co., 339 U.S. at 607 (noting that without the doctrine of equivalents, a copyist may be able to easily avoid literal infringement with a minor change and this would facilitate concealing an invention which is contrary to the one of the goals of the patent law which is public disclosure of patented inventions).

absent.\textsuperscript{160} This doctrine, which the Court characterized as equitable in nature, creates uncertainty because literally inventing around a claim will not insure avoidance of infringement.\textsuperscript{161} The doctrine essentially created a gray area which was bounded on one end by the literal claim limitations but potentially unbounded on the other end. Such uncertainty or lack of predictability, as noted earlier, is an undesirable aspect of a legal system.\textsuperscript{162} However, rather than abandon the judicial doctrine of equivalents, the Supreme Court and the Federal Circuit have slowly evolved specific rules that provide limits on the doctrine so that its scope is somewhat more predictable. The end result is a set of bright-line rules that provide some limits on how far beyond literal infringement a claim can be stretched under the doctrine of equivalents.\textsuperscript{163} Nevertheless, like any rule of law that balances competing interests or policies, a zone of uncertainty exists. This is unavoidable and should not be a basis for rejecting use of a bright-line rule to ascertain statutory subject matter under section 101.

Finally, the disparate effect of the patent law on different industries has long been an issue. Industries such as pharmaceuticals, which typically rely on one or two patents from internal research and

\textsuperscript{160} See, e.g., \textit{Graver Tank & Mfg. Co.}, 339 U.S. at 612 (finding infringement based on the doctrine of equivalents, despite finding no literal infringement). \textit{See generally LANDERS, supra note 11, § 29.01, at 372-73 (noting the balance between preserving an incentive to seek patents with the public notice function of a patent which underlies the patent system).}


\textsuperscript{162} \textit{See id.} at 730-31 (explaining that clear patent claim boundaries promote efficient investment in technology).

\textsuperscript{163} In \textit{Festo Corp.}, 535 U.S. at 733-38, the Court noted that the doctrine of prosecution history estoppel bars a patentee from using the doctrine of equivalents in an infringement action to recapture any part of the claim’s scope that was surrendered or abandoned during prosecution via amendment, in order to overcome objections to patentability. In \textit{Johnson & Johnson Assocs., Inc. v. R.E. Serv. Co.}, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc), the court stated that “when a patent drafter discloses but declines to claim subject matter . . . this action dedicatizes that unclaimed subject matter to the public” and it cannot be recaptured with the doctrine of equivalents. This is generally referred to as the public dedication rule. NARD, \textit{supra} note 129, at 494. In \textit{Wilson Sporting Goods Co. v. David Geoffrey & Assocs.}, 904 F.2d 677, 684 (Fed. Cir. 1990), the court noted that the doctrine of equivalents could not be used to capture prior art. In \textit{Scimed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.}, 242 F.3d 1337, 1345-46 (Fed. Cir. 2001), the court held that if the specification expressly or impliedly excludes something from a claim it cannot be recaptured by the doctrine of equivalents. This is referred to as the specific exclusion rule. NARD, \textit{supra} note 129, at 502. Finally, the all limitations rule is applied so that each limitation in a claim must have a literal or equivalent element in the allegedly infringing device. \textit{Warner-Jenkinson Co. v. Hilton Davis Chem. Co.}, 520 U.S. 17, 29 (1997).
development activities to protect a drug, favor strong patents.164 In contrast, other industries, such as technology and software companies, which produce products that rely on a multitude of patents—many of which must be licensed from third parties—prefer a weaker patent system.165 This issue is not limited to patent law. Typically, any law of general application has the potential to cause this problem. The only potential solution is to enact specific subject-based legislation in lieu of laws of general application. This is unlikely to occur in patent law, whose basic concepts have remained largely unchanged for a long time.166 Additionally, it is doubtful that law would evolve quickly enough to keep pace with rapid changes in technology. Hence, this should likewise not be a reason to reject bright-line rules for determining what is or is not statutory subject matter because the various industries will likely develop marketplace adaptations


165 See id. at 125 (noting that high tech industry, which is largely made up of software companies, favors weak patents).


\section*{VI. Proposed Tests in Addition to the Machine-or-Transformation Test}

In \textit{Bilski} the Supreme Court approved of the machine-or-transformation test, provided it was not used as the sole or controlling test to ascertain whether a process was patent-eligible subject matter.\footnote{\textit{Bilski} v. Kappos, 130 S. Ct. 3218, 3227 (2010) ("This Court's precedents establish that the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101. The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible 'process.'")} In lieu of relying on this test the Court held that the claimed method of hedging was an abstract idea, which was not patent-eligible subject matter.\footnote{Id. at 3230.} Additionally, the Court noted that one of the claims at issue reduced the concept of hedging to a mathematical formula, which is not patent-eligible subject matter.\footnote{Id. at 3231.} The Court also stated that “[a]llowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.”\footnote{Id.} Arguably, the Court’s statements effectively create two tests in addition to the machine-or-transformation test: (a) mathematical formulas are not patent eligible (hereinafter the “equation test”), and (b) the preemption test.\footnote{See id. (holding that hedging is a mathematical formula that is not patent eligible, and that allowing patent protection would preempt the field and monopolize an abstract idea).} This raises two questions: (1) whether the machine-or-transformation test, the equation test, and the preemption test will produce predictable results,\footnote{See generally \textit{id.} at 3227 (suggesting that use of the machine-or-transformation test could have a negative effect on technology such as software and diagnostic medical tests because it could make patentability of such inventions uncertain).} and (2) whether additional tests should be used in lieu of or
in addition to these tests. Arguably, the Bilski Court approves of the Federal Circuit developing additional tests.

A. Statement of the Machine-or-Transformation Test

Under the machine-or-transformation test, a process is statutory subject matter under Patent Law section 101 if either of the following applies: (1) the claim is tied to a particular machine; or (2) the claim transforms an article. Additionally, two limitations apply. First, “the use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility” (hereinafter “preemption rule”). This is sometimes referred to as the preemption test. Second, “the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity” (hereinafter “insignificant limitation rule”).

Legal rules cannot be properly applied in a vacuum. They can only be applied in light of the underlying reasons that justify the rule. The machine-or-transformation test represents an attempt to identify where on the innovation continuum, shown above in Fig. 1, the claimed invention falls. Additionally, the Supreme Court has expressly stated that mathematical formulas and the discovery of something that occurs in nature are not patent-eligible subject matter. However, use of a mathematical formula or a discovery that amounts to an application of that formula or discovery may be patentable because it is further along the invention continuum.

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174 See id. at 3227-28 (suggesting that the inquiry as to a patentable process should not be confined to the machine-or-transformation test, but failing to specify whether such additional inquiries should replace or support the traditional test).

175 See id. at 3231 (“In disapproving an exclusive machine-or-transformation test, we by no means foreclose the Federal Circuit’s development of other limiting criteria that further the purposes of the Patent Act and are not inconsistent with its text.”).


177 Id.

178 Under this test, a process claim is not statutory subject matter if it essentially preempts use of a law of nature or an abstract idea in all contexts. See generally Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012); Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010).


181 See Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (“He who discovers a hitherto unknown phenomenon of nature has no claim to a continued . . .
Hence, the machine-or-transformation test focuses on ascertaining if a machine is part of the process claim; or, in the absence of a machine, whether something is transformed.

The presence of either a machine or a transformation signals that the claimed process is potentially far enough along the invention continuum to be treated as patent-eligible subject matter. Nevertheless, the Court has recognized the practical reality that patent claims can be drafted so that they include extra verbiage to render them literally within the machine-or-transformation test even though the invention should not be treated as patent eligible.\(^{182}\) Therefore, the preemption rule, discussed above, tells a court to look beyond the actual claim language and ascertain whether, despite any limiting language in the claim, the claim in fact really preempts most or all meaningful uses of a mathematical formula, discovery of something that is naturally occurring, or any other non-patentable subject matter. If such preemption occurs, the claim can be treated as an attempt to claim something that is not patent eligible.\(^{183}\)

The insignificant limitation rule, discussed above, recognizes that a claim can include various structural elements and/or transformative steps that may literally satisfy the machine-or-transformation test, but in reality do not provide any significant limitation on the claimed subject matter.

**B. Proposed Tests**

In addition to the machine-or-transformation test for process claims, the following alternative tests are proposed for both product and process claims. Multiple tests are necessary because no single test will produce predictable and consistent results in light of the different types of subject matter that can be patented and the variation in how patent claims are drafted.\(^{184}\) Although failure to satisfy the machine-

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\(^{182}\) Mayo Collaborative Servs., 132 S. Ct. at 1300.

\(^{183}\) See Bilski, 130 S. Ct. at 3231 (concluding that a patent claim covering risk hedging was not patent-eligible subject matter, in part, because the claim would essentially preempt use of hedging generally).

\(^{184}\) See generally id. at 3227 (noting that machine-or-transformation test may be useful for tangible inventions that were typical for the industrial age, but it may not be useful for technological inventions in the current information age).
or-transformation test is not determinative,\textsuperscript{185} it is suggested that failure to satisfy one or more of the following proposed tests should render a claim unpatentable for failure to claim statutory subject matter under Patent Law section 101.

1. Preemption Test and Insignificant Limitation Test

The preemption rule and the insignificant limitation rule, discussed above with regard to the machine-or-transformation test, can be applied independently. Additionally, \textit{Bilski} relied on the preemption rule, in part, in concluding that a claimed method of hedging was not patent-eligible subject matter.\textsuperscript{186} Finally, these rules can be utilized with some or all of the following tests, where appropriate.

2. Equation Test

The Supreme Court has clearly stated that equations such as $E=MC^2$, $F=MA$, or $I=V/R$ are not patent eligible.\textsuperscript{187} Additionally, the \textit{Bilski} Court endorsed finding subject matter ineligible for patent protection if a claim merely covers a mathematical formula.\textsuperscript{188} Therefore, if a claim is merely a disguised attempt to cover a formula or equation, it should be determined that it is not patent-eligible subject matter. This test can be applied broadly by viewing an equation as any type of relationship that is expressed mathematically. If the claim includes, but is not limited to an equation, it is likely patent-eligible subject matter.\textsuperscript{189} The preemption rule, discussed

\textsuperscript{185} Id.

\textsuperscript{186} See id. at 3231 (“[A]llowing petitioners to patent risk hedging would preempt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.”).


\textsuperscript{188} See \textit{Bilski}, 130 S. Ct. at 3231 (“[C]oncept of hedging . . . reduced to a mathematical formula in claim 4, is an unpatentable abstract idea . . . .”).

\textsuperscript{189} See Diamond v. Diehr, 450 U.S. 175, 187 (1981) (“[A] claim drawn to
above, can be used to help ascertain if the claim at issue is only covering an equation. Under this rule, if the claim essentially preempts use of the equation or mathematical relationship in virtually all meaningful contexts, then it is not patent-eligible subject matter. Instead, it is really fundamental knowledge that is part of “the basic tools of scientific and technological work” that is part of the public domain and hence not patent eligible. Additionally, the insignificant limitation rule, discussed above, can also be used. Sometimes a claim contains numerous structural elements or other limitations that make the claim presumptively appear to be claiming more than solely an equation and therefore it is patent eligible. However, these limitations can be examined to determine if they in fact limit the claimed subject matter. The existence of meaningful limits indicates the claim is likely patent-eligible subject matter. Alternatively, the lack of any meaningful limits indicates the claim is directed to ineligible subject matter.

3. Human Intervention Test

The discovery of a new plant species or a new mineral may be very valuable but they are not patent-eligible subject matter. Both of these things are examples of fundamental information or knowledge that are considered part of the public domain that anyone can freely use. Nevertheless, if the discovered item is altered or modified such that it is now in a state that is not naturally available and it has different properties than the naturally available item, it is typically considered patent-eligible subject matter by the U.S. Patent and Trademark Office and the Federal Circuit. An example would be an isolated portion of naturally occurring DNA that has been chemically manipulated to create isolated DNA that is different than subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula . . . .”.

190 See Mayo Collaborative Servs., 132 S. Ct. at 1292.
192 Id.; see also Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).
naturally occurring DNA. The human intervention that changes the naturally occurring thing to a new state has resulted in a novel thing, which is patent eligible. Nevertheless, the preemption test can be applied if the differences between the naturally occurring product and the new product are so insignificant that a patent on the novel product amounts to de facto property rights in the naturally occurring product.

4. Data Comparison Test

A claim that merely includes the act of comparing data should not render the claim unpatentable. However, if the claim solely covers the act of comparing data, it should not be patent-eligible subject matter. Typically, such a claim will control access to naturally occurring phenomena, natural relationships, or mental processes, all of which are outside the domain of patent law protection. As discussed above, both the preemption rule and the insignificant limitation rule can be used to facilitate determining the realistic scope of a claim directed at comparing data.

C. Application of the Proposed Tests to Process Claims

The following analysis looks at several Supreme Court and Court of Appeals for the Federal Circuit decisions that addressed the question of whether specific claims were based on patent-eligible subject matter. The machine-or-transformation test and the other proposed tests, discussed above, are applied to ascertain whether the results comport with the judicial decisions on review in each case.

1. The Prometheus Laboratories Decision

In Prometheus Laboratories, the Court considered the following method claim for optimizing administration of a drug to treat a disorder:

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

195 Id. at 1328; see generally NARD, supra note 129, at 169-70 (discussing how human intervention that isolates and purifies a portion of a naturally occurring gene can render that isolated gene patent-eligible subject matter).

196 See Chakrabarty, 447 U.S. at 309.
having said immune-mediated gastrointestinal disorder . . . wherein the level of 6-thioguanine less than about 230 pmol per $8 \times 10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and . . . wherein the level of 6-thioguanine greater than about 400 pmol per $8 \times 10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.”

This claim, stripped to its bare essence, involves: administration of a specific drug to a patient with a certain disorder, measuring the resulting concentration of the drug in the patient, and then raising or lowering the amount administered in order to achieve a concentration within a specific range. The claim simply compares the measured data with a known range to determine if it is within the required range. Under the proposed data comparison test, this claim would not be considered patent-eligible subject matter because the only thing claimed is the data comparison.

The same result would occur under the proposed preemption test because this claim would essentially prevent anyone from adjusting the dose for the specific medicine in the claim based on the amount present in the person’s blood. The fact that the claim is limited to administering a specific drug for a specific medical disorder—immune-mediated gastrointestinal disorder—is not a sufficient limitation to overcome preemption. At most, this can be viewed as an insignificant limitation, and therefore the insignificant limitation test would also negate patent eligibility.

Likewise, this claim does not survive the machine-or-transformation test. The claim is not tied to a machine, nor is anything transformed via the claim. In contrast, the Federal Circuit found that the second prong of the test was satisfied because the human body, or the blood removed from a person, satisfied the transformation requirement. This analysis was properly rejected by the Supreme

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198 See id. at 1294 (describing the claimed process).
199 See id. at 1298 (stating the claims at issue “simply tell doctors to gather data from which they may draw an inference in light of the correlations.”).
200 Id. at 1294-95 (The amount in a patient’s blood varies because different people metabolize the drug differently).
201 See id. at 1298.
202 Id. at 1296-97.
Such broad application of the test would render it ineffective because very little subject matter would be found unpatentable under such a broad application.

The conclusion, based on the proposed tests, that the above claim is not directed to patent-eligible subject matter disagrees with the Federal Circuit, although it is consistent with the Supreme Court’s conclusion.204

2. The Diehr Decision

In Prometheus Laboratories,205 the Supreme Court, reasoning by analogy, reviewed two prior decisions that analyzed patent eligibility of process claims.206 In Diehr, the Court found that the claims at issue, which referred to the operation of a press as part of an industrial process, satisfied section 101.207 However, in Flook, the Court found that the claim at issue, which was related to a chemical process, was not patent-eligible subject matter.208

One of the representative claims at issue in Diehr stated:

A method of operating a rubber-molding press for precision molded compounds with the aid of a digital computer, comprising: providing said computer with a data base for said press including at least, natural logarithm conversion data (ln), the activation energy constant (C) unique to each batch of said compound being molded, and a constant (x) dependent upon the geometry of the particular mold of the press, initiating an interval timer in said computer upon the closure of the press for monitoring the elapsed time of said closure, constantly determining the temperature (Z) of the mold at a location closely adjacent to the mold

203 Id.
205 Mayo Collaborative Servs., 132 S. Ct. at 1289.
206 Id. at 1298-301.
cavity in the press during molding, constantly providing the computer with the temperature \((Z)\), repetitively calculating in the computer, at frequent intervals during each cure, the Arrhenius equation for reaction time during the cure, which is \(\ln v = CZ + x\) where \(v\) is the total required cure time, repetitively comparing in the computer at said frequent intervals during the cure each said calculation of the total required cure time calculated with the Arrhenius equation and said elapsed time, and opening the press automatically when a said comparison indicates equivalence.\textsuperscript{209}

The above claim involves use of a standard equation known as the Arrhenius equation.\textsuperscript{210} However, it also includes using a computer to perform calculations as part of carrying out an industrial process to make molded rubber products with a press.\textsuperscript{211} Under the equation test, the question is whether this claim is a disguised attempt to claim an equation. Application of the preemption rule indicates that the claim actually covers an industrial process for making molded rubber products, and it does not preempt virtually any uses of the equation. Consequently, in light of these tests, the claim is patent-eligible subject matter.

Applying the machine-or-transformation test produces the same result. The claimed process is tied to a machine—a rubber molding press—and therefore it is presumptively patent-eligible subject matter. As noted above, application of the preemption rule to this claim does not negate patent eligibility. The insignificant limitation rule also does not apply because the various limitations contained in the claim are necessary to carry out the claimed industrial process rather than being mere extraneous and unnecessary verbiage.

The other proposed tests are not applicable to this claim. Therefore, application of the proposed equation test, coupled with the preemption and insignificant limitation tests, agrees with the Supreme Court’s conclusion that the above claim is directed to patent-eligible subject matter.

\textsuperscript{209} Diehr, 450 U.S. at 180 n.5 (quoting from Respondents' application) (superfluous quotation marks omitted).

\textsuperscript{210} See generally Definition of arrhenius-equation, \textsc{Britannica Online Encyclopedia}, http://www.britannica.com/EBchecked/topic/36095/Arrhenius-equation (last visited Mar. 6, 2013) (explaining that this equation is a “mathematical expression that describes the effect of temperature on the velocity of a chemical reaction”). See also Univ. of Cal., Davis, UC Davis ChemWiki, http://chemwiki.ucdavis.edu/Physical_Chemistry/Kinetics/Reaction_Rates/Temperature_Dependence_of_Reaction_Rates/Arrhenius_Equation (last visited Mar. 6, 2013) (containing a detailed discussion of the equation).

\textsuperscript{211} Diehr, 450 U.S. at 180, n.5.
subject matter.\footnote{Id. at 174.}

3. The Flook Decision

The claim at issue in Flook stated:

A method for updating the value of at least one alarm limit on at least one process variable involved in a process comprising the catalytic chemical conversion of hydrocarbons wherein said alarm limit has a current value of \( B_0 + K \) wherein \( B_0 \) is the current alarm base and \( K \) is a predetermined alarm offset which comprises:

1. Determining the present value of said process variable, said present value being defined as \( PVL \); 
2. Determining a new alarm base \( B_1 \), using the following equation: 
   \[ B_1 = B_0(1.0 - F) + PVL(F) \]
   where \( F \) is a predetermined number greater than zero and less than 1.0;
3. Determining an updated alarm limit which is defined as \( B_1 + K \); and thereafter
4. Adjusting said alarm limit to said updated alarm limit value.\footnote{Id. at 585.}

The above claim in Flook is distinguishable from the claim at issue in Diehr. First, under the equation test, the claim in Flook appears to be an attempt to claim a mathematical relationship. In fact, the Flook Court noted that the equation in the claim was a novel mathematical formula discovered by the patent applicant.\footnote{Id. at 596-97.} Although the claim preamble does indicate that it applies to the catalytic chemical conversion of hydrocarbons, no other part of the claim includes any specific structural components or limitations.\footnote{Id. at 596-97.} Instead the claim merely includes a series of steps necessary to perform a calculation that is only, generally tied to the chemical conversion of hydrocarbons.\footnote{See id.} The claim is not limited to a specific industrial process nor does it recite a specific product created by the process.\footnote{See id.} It also does not recite which hydrocarbons are converted, what they are converted into or how the catalytic process is used.\footnote{See id.} Finally, the Court noted:

\begin{itemize}
\item \footnote{Id. at 174.} Id. at 174.
\item \footnote{Flook, 437 U.S. at 596-97 (quoting from Claim 1 of the patent) (superfluous quotation marks omitted).} Flook, 437 U.S. at 596-97 (quoting from Claim 1 of the patent) (superfluous quotation marks omitted).
\item \footnote{Id. at 585.} Id. at 585.
\item \footnote{Id. at 596-97.} Id. at 596-97.
\item \footnote{See id.} See id.
\item \footnote{See id.} See id.
\item \footnote{See id.} See id.
\end{itemize}
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. All that it provides is a formula for computing an updated alarm limit.\(^\text{219}\)

In light of the above holding in *Flook*, under the preemption test, this claim would not be patent-eligible subject matter because it is an attempt to claim the use of a specific mathematical relationship in any process that involves converting hydrocarbons into another state via the use of any type of catalytic chemical conversion.

Under the first prong of the machine-or-transformation test, the claim is also not statutory subject matter because the process is not tied to a machine. However, under the second prong of the test it could be argued that hydrocarbons are transformed. Nevertheless, as noted above, the preemption rule, which is a limitation on the machine-or-transformation test, would render the claim non-statutory subject matter.

Therefore, application of the proposed equation test modified by the preemption test produces the same result as the Supreme Court’s conclusion;\(^\text{220}\) the above claim is not directed to patent-eligible subject matter.

4. *The Metabolite Decision*

In *Metabolite Laboratories, Inc. v. Laboratory Corp. of American Holdings,*\(^\text{221}\) the court considered the following claim for a diagnostic test for detecting a vitamin deficiency: “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.”\(^\text{222}\) At the most basic level this method involves measuring a specific body fluid—homocysteine—which is a naturally occurring

\(^{219}\) *Id.* at 586.

\(^{220}\) *Id.* at 594.


\(^{222}\) *Id.* at 1358-59.
amino acid found in blood.\textsuperscript{223} If the homocysteine level is elevated, it is known that the person has a deficiency of cobalamin or folate, which is commonly referred to as vitamin B-12.\textsuperscript{224} So in essence, a person’s homocysteine level is measured and is then compared to a normal level; if it is elevated, the person has a vitamin deficiency, and if it is not elevated, there is no vitamin deficiency.\textsuperscript{225}

This claim does not pass muster under the first prong of the machine-or-transformation test because no machine of any type is involved in the claim. Additionally, it fails under the second prong because nothing is transformed. The “assaying” step merely refers to analyzing the body fluid to determine the amount of homocysteine present,\textsuperscript{226} and the “correlating” step merely refers to comparing the measured homocysteine level with a normal level.

Additionally, this claim is not patent-eligible subject matter under the proposed data comparison test because the act of comparing data is the sole thing it claims. It would also fail the proposed preemption test because this claim prevents anyone from using the naturally occurring correlation that exists between homocysteine and vitamin B-12.

Ultimately, this claim was upheld as valid on other grounds because the issue of statutory subject matter was raised for the first time in the writ of certiorari filed with the Supreme Court.\textsuperscript{227} Although the writ was initially granted on the question of whether this claim was made patent ineligible by violating the prohibition on patenting “laws of nature, natural phenomena, and abstract ideas,”\textsuperscript{228} the Court subsequently dismissed the writ.\textsuperscript{229}

Based on the above analysis using the proposed data comparison test, the claim is not patent-eligible subject matter. Interestingly, at least three Supreme Court justices agreed with this conclusion in a non-binding dissenting opinion, which accompanied the dismissal of

\textsuperscript{225} Metabolite Labs., Inc., 370 F.3d at 1363-64 (holding that when interpreting this claim that the step of “correlating” meant “comparing the elevated [homocysteine] level with the normal homocysteine level.”).
\textsuperscript{228} Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 543 U.S. 1185 (2005).
\textsuperscript{229} Lab. Corp. of Am. Holdings, 548 U.S. at 124.
5. The Biogen Idec Decision

Several recent Federal Circuit decisions seem to reach inconsistent results. In *Classen Immunotherapies, Inc. v. Biogen Idec*, the court reviewed the patent eligibility of the claims in three related patents. The district court originally found the claims to be non-statutory subject matter under section 101. The Federal Circuit affirmed that result, but the Supreme Court vacated the decision and remanded it for reconsideration in light of its decision in *Bilski*. Following the remand, the Federal Circuit held that the following claim for evaluating the effectiveness of an immunization schedule was not statutory subject matter:

A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

In contrast, the court held that the following claim related to immunization scheduling was statutory subject matter:

A method of immunizing a mammalian subject which comprises:

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230 *Id.* at 134-38 (Justice Breyer, whose dissenting opinion was joined by Justices Stevens and Souter, makes it clear that he believes the claim at issue is not patent-eligible subject matter).


232 *Id.* at 1060.


234 *Id.*


236 *Classen Immunotherapies, Inc.*, 659 F.3d at 1065.

237 *Id.* at 1061 (quoting from Claim 1 of the ‘283 patent).

238 *Id.* at 1065.
(I) screening a plurality of immunization schedules, by
(a) identifying a first group of mammals and at least a
second group of mammals, said mammals being of the
same species, the first group of mammals having been
immunized with one or more doses of one or more
infectious disease-causing organism-associated
immunogens according to a first screened
immunization schedule, and the second group of
mammals having been immunized with one or more
doses of one or more infectious disease-causing
organism-associated immunogens according to a
second screened immunization schedule, each group of
mammals having been immunized according to a
different immunization schedule, and
(b) comparing the effectiveness of said first and second
screened immunization schedules in protecting against
or inducing a chronic immune-mediated disorder in
said first and second groups, as a result of which one of
said screened immunization schedules may be
identified as a lower risk screened immunization
schedule and the other of said screened schedules as a
higher risk screened immunization schedule with regard
to the risk of developing said chronic immune mediated
disorder(s),
(II) immunizing said subject according to a subject
immunization schedule, according to which at least one
of said infectious disease-causing organism-associated
immunogens of said lower risk schedule is
administered in accordance with said lower risk
screened immunization schedule, which administration
is associated with a lower risk of development of said
chronic immune-mediated disorder(s) than when said
immunogen was administered according to said higher
risk screened immunization schedule.  

Contrary to the Federal Circuit, I would argue that both of the
above claims merely cover a comparison of data that yields useful
information for combating disease via immunization.  Under the
proposed data comparison test, both claims should be found deficient
under section 101 because neither claim is directed to anything more
than making data comparisons.  Arguably, application of the machine-

\[239\] Id. at 1060-61 (quoting from Claim 1 of the ‘739 patent).
or-transformation test would support finding neither claim to be patent-eligible subject matter since neither claim is tied to a machine, and neither involve a transformation of anything.240

6. The PerkinElmer Decision

In *PerkinElmer, Inc. v. Intema Ltd.*, 241 the Federal Circuit concluded that the following claim for determining the risk of giving birth to a child with Down’s syndrome was not patent-eligible subject matter.242

A method of determining whether a pregnant woman is at an increased risk of having a fetus with Down’s syndrome, the method comprising the steps of: measuring the level of at least one screening marker from a first trimester of pregnancy by: (i) assaying a sample obtained from the pregnant woman at said first trimester of pregnancy for at least one first biochemical screening marker; and/or (ii) measuring at least one first ultrasound screening marker from an ultrasound scan taken at said first trimester of pregnancy; measuring the level of at least one second screening marker from a second trimester of pregnancy, the at least one second screening marker from the second trimester of pregnancy being different from the at least one first screening marker from the first trimester of pregnancy, by: (i) assaying a sample obtained from the pregnant woman at said second trimester of pregnancy for at least one second biochemical screening marker; and/or (ii) measuring at least one second ultrasound screening marker from an ultrasound scan taken at said second trimester of pregnancy; and determining the risk of Down’s syndrome by comparing the measured levels of both the at least one first screening marker from the first trimester of pregnancy and the at least one second screening marker from the second trimester of pregnancy with observed relative frequency distributions of marker levels in Down’s syndrome

240 Classen Immunotherapies, Inc. v. Biogen Idec, 304 F. App’x. 866 (Fed. Cir. 2008), vacated, 130 S. Ct. 3541 (2010) (The Federal Circuit initially reached this conclusion prior to the case being vacated and remanded by the Supreme Court.).
242 Id. at *1-2.
pregnancies and in unaffected pregnancies.\textsuperscript{243}

The above claim solely involves obtaining certain biological data from a pregnant woman during her first and second trimesters of pregnancy, and then comparing that data to predict whether she is at an increased risk of giving birth to a baby with Down’s syndrome.\textsuperscript{244}

The court was correct in finding that this claim does not cover patent-eligible subject matter. The same result would be reached under the proposed data comparison test. Arguably, the machine-or-transformation test would also support the same conclusion because the claim does not involve any machine, or a transformation of anything.

7. The Association for Molecular Pathology Decision

In \textit{Association for Molecular Pathology v. U.S. P.T.O.},\textsuperscript{245} the Federal Circuit held that the following claim for a method of screening for breast cancer did not cover patent-eligible subject matter:\textsuperscript{246}

A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprises \textit{[ ] comparing} a first sequence selected from the group consisting of a BRCA1 gene from said tumor sample, BRCA1 RNA from said tumor sample and BRCA1 cDNA made from mRNA from said tumor sample with a second sequence selected from the group consisting of BRCA1 gene from a nontumor sample of said subject, BRCA1 RNA from said nontumor sample and BRCA1 cDNA made from mRNA from said nontumor sample, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said tumor sample from the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said nontumor sample indicates a somatic alteration in the BRCA1 gene in said tumor sample.\textsuperscript{247}

\textsuperscript{243} U.S. Patent No. 6,573,103, claim 1 (filed Apr. 29, 1999) (issued June 3, 2003). \textit{See also id.} at *2-3 (citing an abbreviated portion of the claim).

\textsuperscript{244} \textit{PerkinElmer, Inc.}, 2012 U.S. App. LEXIS 23845 at *2.

\textsuperscript{245} Ass’n Molecular Pathology v. U.S. P.T.O., 689 F.3d 1303, 1309-10 (Fed. Cir. 2012), \textit{cert. granted sub nom.}, Ass’n Molecular Pathology v. Myriad Genetics, 133 S. Ct. 694 (2012).

\textsuperscript{246} \textit{See id.} at 1333.

\textsuperscript{247} \textit{Id.} at 1310 (quoting from Claim 1 of the ‘999 patent).
The court noted that this claim was merely related to comparing data to screen individuals for breast cancer.\(^{248}\) Therefore, the court concluded that because the claim amounted to no more than obtaining and comparing data, it was not patent eligible.\(^{249}\)

In contrast to the above result, the Federal Circuit held in the same decision that the following claim for screening cancer therapeutics was directed to patent-eligible subject matter:\(^{250}\)

A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said transformed eukaryotic host cell in the absence of said compound, determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.\(^{251}\)

A cursory examination of claims 1 and 20, quoted above respectively, indicates they both involve obtaining and comparing data to predict a result. However, the court finds a distinction between the two claims; it concludes that claim 1 only requires the comparison of data,\(^{252}\) but that claim 20 requires the creation of a transformed eukaryotic host cell, which is then used to obtain and compare the resulting data.\(^{253}\) This host cell is not a naturally occurring cell;\(^{254}\) it is essentially created in a laboratory via human intervention. Therefore, as the court notes, it is analogous to the Supreme Court’s decision in *Diamond v. Chakrabarty*,\(^{255}\) which held that an artificially created life-

\(^{248}\) *Id.* at 1334.

\(^{249}\) *Id.* at 1334-35.

\(^{250}\) *Id.* at 1337.

\(^{251}\) *Id.* at 1310 (quoting from Claim 20 of the ‘282 patent).

\(^{252}\) *Id.* at 1335.

\(^{253}\) *Id.* at 1336-37.

\(^{254}\) *Id.* at 1335-36.

\(^{255}\) *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). See *Ass’n Molecular Pathology*, 689 F.3d at 1336 (“Claim 20 thus recites a screening method premised on the use of ‘transformed’ host cells. Those cells, like the patent-eligible cells in *Chakrabarty*, are not naturally occurring. Rather, they are derived by altering a cell to include a foreign gene, resulting in a man-made, transformed cell with enhanced function and utility.”).
form was statutory subject matter because it was not naturally occurring.\textsuperscript{256} Hence, claim 20 essentially requires creating a non-naturally occurring cell, which is then used to obtain data. That data is subsequently compared for screening potential cancer treatments. Consequently, claim 20 is directed to patent-eligible subject matter, but claim 1 is directed to non-statutory subject matter. Based on the factual assertions by the court, its conclusions appear to be correct.

Applying the proposed tests leads to the same conclusions as those reached in the Federal Circuit decision. Claim 1 would be held to be non-patentable subject matter under the data comparison test. In contrast, claim 20 would be patent eligible because it requires more than merely comparing data; it requires the creation of a non-naturally occurring host cell,\textsuperscript{257} and therefore, under the proposed human intervention test, it would be patent-eligible subject matter. If the machine-or-transformation test is applied, the result will arguably be consistent with this analysis. Claim 1 does not involve either a machine or a transformation of anything, but claim 20 arguably involves transforming a naturally occurring cell into a non-naturally occurring cell. Therefore, the machine-or-transformation test would negate claim 1 but uphold claim 20.

8. The Bilski Decision

In Bilski, the Supreme Court found that a business method claim\textsuperscript{258} for hedging\textsuperscript{259} was not patent-eligible subject matter.\textsuperscript{260} Both the

\textsuperscript{256}Chakrabarty, 447 U.S. at 309-10.

\textsuperscript{257}In contrast, although claim 1 in Ass ’n for Molecular Pathology requires the creation of “BRAC1 cDNA made from mRNA” for both the tumor and the non-tumor samples, both cDNA and mRNA are naturally occurring, although they can also be artificially synthesized. A gene or other genetic material is not patent-eligible subject matter in its naturally occurring state. See Craig Nard, The Law of Patents 169 (2d ed. 2011). But if such material is isolated and purified so that it exists in a form or state that does not occur in nature, it is potentially patent-eligible subject matter. Id. U.S. Patent and Trademark Office guidelines state that “an inventor’s discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.” Id.

\textsuperscript{258}Bilski v. Kappos, 130 S. Ct. 3218, 3228-29 (noting that the category of business method claims was not per se non-statutory subject matter under section 101).

\textsuperscript{259}See id. at 3223 (Hedging is a method of minimizing the risk of price changes.). See also Hedging, Britannica Online Encyclopedia, http://www.britannica.com/EBchecked/topic/259286/hedging (last visited Dec. 31, 2012).

\textsuperscript{260}Bilski, 130 S. Ct. at 3230 (“[A]ll members of the Court agree that the patent application at issue here falls outside of § 101 because it claims an abstract idea.”).
Patent and Trademark Office and the Federal Circuit had previously reached the same conclusion. One of the claims at issue stated:

A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:

(a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;
(b) identifying market participants for said commodity having a counter-risk position to said consumers; and
(c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.

The Supreme Court deemed the above claim to be an attempt to claim hedging. The Court then concluded that hedging was merely an abstract idea, and therefore not patent eligible. However, the Court did not provide a specific test or criteria for ascertaining whether a claim is, or is not, directed to an abstract idea. Arguably, the Court was using a test akin to the proposed equation test when it stated that the above claim, as a practical matter, reduced the concept of hedging to a mathematical formula, which is not patent eligible subject matter. It also relied on the proposed preemption test when it concluded that the claim at issue would preempt the use of the abstract idea of hedging. Ultimately, the Court’s holding, as noted above, is consistent with the results of using the proposed tests.

Application of the machine-or-transformation test, although not determinative, also supports the Court’s conclusion because the claim does not include the use of any machine, nor does it transform anything. The claim only involves buying and selling commodities such that any risk of loss is hedged.

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261 Id. at 3224.
263 Bilski, 130 S. Ct. at 3231.
264 Id. at 3230.
265 See id. at 3231.
266 See id.
9. The In re Comiskey Decision

The Federal Circuit, sitting en banc, found the following claim to cover a business method in the form of mandatory arbitration:

A method for mandatory arbitration resolution regarding one or more unilateral documents comprising the steps of: enrolling a person and one or more unilateral documents associated with the person in a mandatory arbitration system at a time prior to or as of the time of creation of or execution of the one or more unilateral documents; incorporating arbitration language, that is specific to the enrolled person, in the previously enrolled unilateral document wherein the arbitration language provides that any contested issue related to the unilateral document must be presented to the mandatory arbitration system, in which the person and the one or more unilateral documents are enrolled, for binding arbitration wherein the contested issue comprises one or more of a challenge to the documents, interpretation of the documents, interpretation or application of terms of the documents and execution of the documents or terms of the documents; requiring a complainant to submit a request for arbitration resolution to the mandatory arbitration system wherein the request is directed to the contested issue related to the unilateral document containing the arbitration language; conducting arbitration resolution for the contested issue related to the unilateral document in response to the request for arbitration resolution; providing support to the arbitration resolution; and determining an award or a decision for the contested issue related to the unilateral document in accordance with the incorporated arbitration language, wherein the award or the decision is final and binding with respect to the complainant.

The court’s conclusion that the above claim is not patent-eligible subject matter was based on finding that the claim merely covered a mental process for resolving a dispute via arbitration. Additionally, the court noted that the parties conceded that the claim would not

\[267\] In re Comiskey, 554 F.3d 967, 975-76 (Fed. Cir. 2009) (en banc).

\[268\] Id. at 970 n.1 (quoting from Claim 1 of the ‘742 patent application).

\[269\] Id. at 981.
survive the machine-or-transformation test.\textsuperscript{270}

\textit{10. The CLS Bank International Decision}

In this case, the following business method claim was analyzed to determine if it was patent-eligible subject matter:

A method of exchanging obligations as between parties, each party holding a credit record and a debit record with an exchange institution, the credit records and debit records for exchange of predetermined obligations, the method comprising the steps of:
(a) creating a shadow credit record and a shadow debit record for each stakeholder party to be held independently by a supervisory institution from the exchange institutions;
(b) obtaining from each exchange institution a start-of-day balance for each shadow credit record and shadow debit record;
(c) for every transaction resulting in an exchange obligation, the supervisory institution adjusting each respective party's shadow credit record or shadow debit record, allowing only these [sic] transactions that do not result in the value of the shadow debit record being less than the value of the shadow credit record at any time, each said adjustment taking place in chronological order; and
(d) at the end-of-day, the supervisory institution instructing one of the exchange institutions to exchange credits or debits to the credit record and debit record of the respective parties in accordance with the adjustments of the said permitted transactions, the credits and debits being irrevocable, time invariant obligations placed on the exchange institutions.\textsuperscript{271}

The district court concluded that the above claim was not patent-

\textsuperscript{270} \textit{See id.} (conceding the claims do not require a machine, they do not describe a manufacturing process, nor do they include a process that alters a composition of matter).

\textsuperscript{271} CLS Bank Int'l v. Alice Corp. Pty. Ltd., 685 F.3d 1341, 1343-44 (Fed. Cir. 2012) (quoting from Claim 33 of the '479 patent), \textit{vacated & reh'g en banc granted}, 484 F. App’x 559 (Fed. Cir. 2012).
eligible subject matter. The Federal Circuit initially disagreed and determined that the claim was patent-eligible subject matter. The court’s reasoning was based on its finding that the above claim was directed to more than an abstract idea. The court held that it claimed a practical application of a business method, which required implementation on a computer. Additionally, the court noted that, because the claim would have to be implemented on a computer, it would likely satisfy the machine prong of the machine-or-transformation test. Subsequently, the Federal Circuit vacated this decision and agreed to rehear the case en banc.

Under the proposed preemption test, it can be argued that the above claim is not directed to patent-eligible subject matter. The claimed business method can be described as:

a computerized trading platform for exchanging obligations in which a trusted third party settles obligations between a first and second party so as to eliminate “settlement risk.” Settlement risk is the risk that only one party’s obligation will be paid, leaving the other party without its principal. The trusted third party eliminates this risk by either (a) exchanging both parties’ obligations or (b) exchanging neither obligation.

Any requirement that this method must be performed on a computer is not a realistic limitation because any modern financial transaction of this type would only be viable if it utilized a computer system. This limitation, therefore, is not relevant under the insignificant limitation test. Additionally, under the proposed preemption test, this claim would not be patent-eligible subject matter because it would preempt the basic idea of using a trusted third party to hold assets that will only be distributed under certain circumstances. This is a basic and commonly used idea which is analogous to the typical arrangement used in real estate transactions. Moreover, the

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272 Id. at 1345.
273 Id. at 1343.
274 See id. at 1346-47 (holding that this claim was patent-eligible subject matter after stating that abstract ideas are not patent-eligible subject matter).
275 Id. at 1355.
276 Id.
279 JOHN SPRANKLING AND RAYMOND COLETTA, PROPERTY—A CONTEMPORARY APPROACH 562 (2d ed. 2012) (In many states an escrow agent acts continued . . .
claimed business method involves comparing various data to determine if an obligation should be honored by a financial institution. Arguably, this may cause the method to also be considered not patent-eligible subject matter under the proposed data comparison test.

D. Application of the Proposed Tests to Product Claims

1. The Association for Molecular Pathology Decision

In addition to the process claims discussed above, the Association for Molecular Pathology case also involved several “composition of matter” claims directed to isolated DNA molecules.\(^\text{280}\) The following is a representative claim which was held to be patent-eligible subject matter by the Federal Circuit:\(^\text{281}\) “An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.”\(^\text{282}\) The court concluded that this claim covered a patent eligible composition of matter and explained:

The [claimed] isolated DNA molecules before us are not found in nature. They are obtained in the laboratory and are man-made, the product of human ingenuity. While they are prepared from products of nature, so is every other composition of matter. All new chemical or biological molecules, whether made by synthesis or decomposition, are made from natural materials. For example, virtually every medicine utilized by today’s medical practitioners, and every manufactured plastic product, is either synthesized from natural materials (most often petroleum fractions) or derived from natural plant materials. But, as such, they are different from natural materials, even if they are ultimately derived from them. The same is true of isolated DNA molecules.\(^\text{283}\)

The court’s holding is consistent with the proposed human intervention test which is based on the Supreme Court decision in

\[^{280}\text{Ass’n Molecular Pathology v. U.S.P.T.O., 689 F.3d 1303, 1309 (Fed. Cir. 2012) cert. granted sub nom. Ass’n Molecular Pathology v. Myriad Genetics, 133 S. Ct. 694 (2012).}\]
\[^{281}\text{Id. at 1325.}\]
\[^{282}\text{Id. at 1309 (quoting Claim 1 of the ‘282 patent).}\]
\[^{283}\text{Id. at 1325.}\]
Nevertheless, the proposed preemption test may negate patent eligibility. Under that test, if the above claim on an isolated DNA molecule would prevent anyone from utilizing that DNA in its natural state, then the claim is not statutory subject matter. The application of this test to the above claim turns on a factual question: is the claimed DNA so similar to the naturally occurring DNA that allowance of the claim essentially preempts others from utilizing the naturally occurring DNA? If the answer is yes, the claim should be held to be not patent-eligible subject matter. If the answer is no, the claim was correctly found to be patent-eligible subject matter by the Federal Circuit.

2. The State Street Bank Decision

This Federal Circuit decision, which categorically stated that business method patents were not per se invalid, actually involved a product claim, not a business method claim. The following claim was at issue:

A data processing system for managing a financial services configuration of a portfolio established as a partnership, each partner being one of a plurality of funds, comprising:
(a) computer processor means [a personal computer including a CPU] for processing data;
(b) storage means [a data disk] for storing data on a storage medium;
(c) first means [an arithmetic logic circuit configured to prepare the data disk to magnetically store selected data] for initializing the storage medium;
(d) second means [an arithmetic logic circuit configured to retrieve information from a specific file, calculate incremental increases or decreases based on specific input, allocate the results on a percentage basis, and store the output in a separate file] for processing

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284 See, e.g., Douglas L. Rogers, Coding For Life—Should Any Entity Have The Exclusive Right To Use And Sell Isolated DNA?, 12 U. PITT. J. TECH. & POL’Y 1, 23-24 (2011) (inquiring whether or not “purification [is] the kind of human intervention into naturally occurring products that the Supreme Court in Chakrabarty contemplated as the dividing between patentable and unpatentable subject matter?”).
286 Id. at 1375.
287 Id. at 1371 (illustrating claim at issue directed to a machine).
data regarding assets in the portfolio and each of the funds from a previous day and data regarding increases or decreases in each of the funds, [sic, funds'] assets and for allocating the percentage share that each fund holds in the portfolio;

(e) third means [an arithmetic logic circuit configured to retrieve information from a specific file, calculate incremental increases and decreases based on specific input, allocate the results on a percentage basis and store the output in a separate file] for processing data regarding daily incremental income, expenses, and net realized gain or loss for the portfolio and for allocating such data among each fund;

(f) fourth means [an arithmetic logic circuit configured to retrieve information from a specific file, calculate incremental increases and decreases based on specific input, allocate the results on a percentage basis and store the output in a separate file] for processing data regarding daily net unrealized gain or loss for the portfolio and for allocating such data among each fund; and

(g) fifth means [an arithmetic logic circuit configured to retrieve information from specific files, calculate that information on an aggregate basis and store the output in a separate file] for processing data regarding aggregate year-end income, expenses, and capital gain or loss for the portfolio and each of the funds. \(^{288}\)

The above claim is for a machine, which makes rapid calculations with regard to a pool of mutual funds. \(^{289}\) Such rapid calculations are necessary \(^{290}\) to obtain certain tax advantages and economies of scale with regard to a financial product. \(^{291}\) A careful examination of the claim indicates it involves having a computer make a series of calculations, and then outputting the data to a computer file.

The broad nature of the claim essentially covers an algorithm based on a variety of data sources. In essence, this claim is no more than an attempt to claim data calculations, which is akin to claiming an equation. Under the proposed equation test, this claim therefore does

\(^{288}\) Id. at 1371-72 (quoting Claim 1 of the ‘056 patent).

\(^{289}\) Id. at 1370.

\(^{290}\) Id. at 1371.

\(^{291}\) See id. at 1370 (providing a brief explanation of the financial product at issue).
not cover patent-eligible subject matter.

Although it could correctly be argued that this claim is specifically limited to performing the calculations on a computer system, such a limitation is inadequate to convert this claim into statutory subject matter. From a practical perspective, the necessary calculations in the claim can only be easily performed on a computer. Additionally, it is the speed with which a computer is able to carry out the claimed calculations that make the system viable. Hence, this claim could arguably also be considered patent ineligible subject matter under the proposed preemption test because it preempts all realistic use of the claimed calculations. Moreover, the claim limitations requiring use of a computer can also be viewed as insignificant limitations.

As a result, under the proposed tests, this claim would be directed to non-statutory subject matter, the opposite conclusion of the one reached by the Federal Circuit.

VII. CONCLUSION

The determination of what subject matter is potentially eligible for patent protection has long been, and continues to be, an unclear issue. Patent law specifically identifies four broad categories of subject matter—process, machine, manufacture, or composition of matter—that are patent eligible. Although very few things fall outside these categories, the Supreme Court has engrafted some exceptions and limitations onto these statutory categories. Patentable subject matter that is otherwise within these categories is deemed not to be patent eligible if it is a “law of nature,” a “physical phenomenon,” or an “abstract idea.” The precise meaning or scope of these limitations is difficult to enunciate despite numerous Supreme Court and lower court decisions, which have attempted to define these terms. Nevertheless, these limitations can be viewed merely as labels that are attached after a judicial balance has been made between competing or conflicting underlying concepts: providing patent protection to promote innovation, and denying patent protection when it disincentives innovative activities. Early stage research often produces discoveries such as previously unknown mathematical relationships, fundamental concepts, physical forces, biological data, or correlations. These discoveries are fundamental building blocks which are very valuable starting points for engaging in future research that will lead to new technological products and processes that have real world practical applications. Such discoveries are denied patent protection because they are potentially too valuable. Granting patent protection would ultimately impede future innovation based on these building blocks. Hence, fundamental building blocks are labeled as a
“law of nature,” a “physical phenomenon,” or an “abstract idea” to signify they are not patent-eligible subject matter. Once the level of innovation and development moves far enough downstream on the innovation continuum, the subject matter becomes patent eligible. Divining the precise point on the innovation continuum where the divide between patent-eligible and unpatrientable subject matter occurs has eluded courts.

This article asserts that the commercial importance of patents in the modern marketplace strongly favors predictable determinations of what is, and what is not patent-eligible subject matter. This can only be accomplished via relatively bright-line rules which may be over- or under-inclusive, and which may have disparate and potentially inequitable impacts on different industries. Analogous to other areas of law, these potential problems are outweighed by the importance of having predictable results.

The variety of new technology, and the multitude of ways patent claims are drafted make it impossible to create a single rule for ascertaining whether something is patent-eligible subject matter. Therefore, this article proposes a number of different tests where failure to satisfy any one of the tests negates patent eligibility. These tests include the preemption test, which holds that a claim is not patent eligible if it essentially preempts all meaningful use of a law of nature, natural phenomena, or an abstract idea in substantially all contexts. The insignificant limitation test helps to recognize inclusion of limitations in claims that appear to limit claim scope, but in fact do not provide any significant practical limitation on claim scope, and therefore, the claim should be determined to cover unpatentable subject matter. The equation test disallows a claim that amounts to no more than a disguised attempt to claim a formula, equation, or mathematical relationship. The human intervention test provides that a fundamental discovery of something, such as a new plant species, a new mineral, a new compound, or a new biological material, is patent eligible if it is altered or modified so that it is in a non-naturally occurring state and has properties that are not exhibited in its naturally occurring form. Finally, the data comparison test negates patent eligibility if a claim merely covers the act of comparing data without more.