

2106 Patent Subject Matter Eligibility [R-11.2013]

There are two criteria for determining subject matter eligibility and both must be satisfied. The claimed invention (1) must be directed to one of the four statutory categories, and (2) must not be wholly directed to subject matter encompassing a judicially recognized exception, as defined below. The following two step analysis is used to evaluate these criteria.

I. THE FOUR CATEGORIES OF STATUTORY SUBJECT MATTER

Step 1: Is the claim directed to one of the four patent-eligible subject matter categories: process, machine, manufacture, or composition of matter? The subject matter of the claim must be directed to one of the four subject matter categories. If it is not, the claim is not eligible for patent protection and should be rejected under [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#), for at least this reason. A summary of the four categories of invention, as they have been defined by the courts, are:

- i. Process – an act, or a series of acts or steps. See *Gottschalk v. Benson*, 409 U.S. 63, 70, 175 USPQ 673, 676 (1972) ("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." (emphasis added) (quoting *Cochrane v. Deener*, 94 U.S. 780, 788, 24 L. Ed. 139, 1877 Dec. Comm'r Pat. 242 (1876)); *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1316, 75 USPQ2d 1763, 1791 (Fed. Cir. 2005) ("[A] process is a series of acts." (quoting *Minton v. Natl. Ass'n. of Securities Dealers*, 336 F.3d 1373, 336 F.3d 1373, 1378, 67 USPQ2d 1614, 1681 (Fed. Cir. 2003))). See also [35 U.S.C. 100\(b\) \(mpep-9015-appx-l.html#d0e302350\)](#); *Biilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218, 95 USPQ2d 1001 (2010).
- ii. Machine – a concrete thing, consisting of parts, or of certain devices and combination of devices. *Burr v. Duryee*, 68 U.S. (1 Wall.) 531, 570, 17 L. Ed. 650 (1863). This includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result. *Coming v. Burden*, 56 U.S. 252, 267, 14 L. Ed. 683 (1854).
- iii. Manufacture – an article produced from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by handlabor or by machinery. *Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 USPQ 193, 197 (1980) (emphasis added) (quoting *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11, 51 S. Ct. 328, 75 L. Ed. 801, 1931 (Dec. Comm'r Pat. 711 (1931))).
- iv. Composition of matter – 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, for example. *Chakrabarty*, 447 U.S. at 308, 206 USPQ at 197.

Non-limiting examples of claims that are not directed to one of the statutory categories:

- i. transitory forms of signal transmission (for example, a propagating electrical or electromagnetic signal *per se*), *In re Nuijten*, 500 F.3d 1346, 1357, 84 USPQ2d 1495, 1503 (Fed. Cir. 2007);
- ii. a naturally occurring organism, *Chakrabarty*, 447 U.S. at 308, 206 USPQ at 197;
- iii. a human *per se*, The Leahy-Smith America Invents Act (AIA), Public Law 112-29, [sec. 33 \(mpep-9015-appx-l.html#aiasec33limitonissuance\)](#), 125 Stat. 284 (September 16, 2011);
- iv. a legal contractual agreement between two parties, see *In re Ferguson*, 558 F.3d 1359, 1364, 90 USPQ2d 1035, 1039-40 (Fed. Cir. 2009) (cert. denied);
- v. a game defined as a set of rules;
- vi. a computer program *per se*, *Gottschalk v. Benson*, 409 U.S. at 72, 175 USPQ at 676-77;
- vii. a company, *Ferguson*, 558 F.3d at 1366, USPQ at 1040; and
- viii. a mere arrangement of printed matter, *In re Miller*, 418 F.2d 1392, 1396, 164 USPQ 46, 49 (CCPA 1969).

A claim that covers both statutory and non-statutory embodiments (under the broadest reasonable interpretation of the claim when read in light of the specification and in view of one skilled in the art) embraces subject matter that is not eligible for patent protection and therefore is directed to non-statutory subject matter. Such claims fail the first step and should be rejected under [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#), for at least this reason.

For example, machine readable media can encompass non-statutory transitory forms of signal transmission, such as, a propagating electrical or electromagnetic signal *per se*. See *In re Nuijten*, 500 F.3d 1346, 84 USPQ2d 1495 (Fed. Cir. 2007). When the broadest reasonable interpretation of machine readable media in light of the specification as it would be interpreted by one of ordinary skill in the art encompasses transitory forms of signal transmission, a rejection under [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#) as failing to claim statutory subject matter would be appropriate. Thus, a claim to a computer readable medium that can be a compact disc or a carrier wave covers a non-statutory embodiment and therefore should be rejected under [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#) as being directed to non-statutory subject matter.

If the claimed invention is clearly not within one of the four categories, it is not patent eligible. However, when the claim fails under Step 1 and it appears from applicant's disclosure that the claim could be amended to be directed to a statutory category, Step 2 below should still be conducted.

II. JUDICIAL EXCEPTIONS TO THE FOUR CATEGORIES

Step 2: Does the claim wholly embrace a judicially recognized exception, which includes laws of nature, physical phenomena, and abstract ideas, or is it a particular practical application of a judicial exception? See *Bilski v. Kappos*, 561 U.S. ___, ___, 130 S. Ct. 3218, 3225, 95 USPQ2d 1001, 1005-06 (2010) (stating “The Court’s precedents provide three specific exceptions to [§ 101 \(mpep-9015-appx-l.html#d0e302376\)](#)’s broad patent-eligibility principles: ‘laws of nature, physical phenomena, and abstract ideas.’”) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 206 USPQ 193, 197 (1980)).

Determining whether the claim falls within one of the four enumerated categories of patentable subject matter recited in [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#) (i.e., process, machine, manufacture, or composition of matter) does not end the analysis because claims directed to nothing more than abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature are not eligible for patent protection. *Diamond v. Diehr*, 450 U.S. 175, 185, 209 USPQ 1, 7 (1981); accord, e.g., *Chakrabarty*, 447 U.S. at 309, 206 USPQ at 197; *Parker v. Flook*, 437 U.S. 584, 589, 198 USPQ 193, 197 (1978); *Benson*, 409 U.S. at 67-68, 175 USPQ at 675. “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.” *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852). Instead, such “manifestations of laws of nature” are “part of the storehouse of knowledge,” “free to all men and reserved exclusively to none.” *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130, 76 USPQ 280, 281 (1948).

Thus, “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter” under [Section 101 \(mpep-9015-appx-l.html#d0e302376\)](#). *Chakrabarty*, 447 U.S. at 309, 206 USPQ at 197. “Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.” *Id.* Nor can one patent “a novel and useful mathematical formula,” *Flook*, 437 U.S. at 585, 198 USPQ at 195; electromagnetism or steam power, *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 113-114 (1853); or “[t]he qualities of ... bacteria, ... the heat of the sun, electricity, or the qualities of metals,” *Funk*, 333 U.S. at 130, 76 USPQ at 281; see *Le Roy*, 55 U.S. (14 How.) at 175.

While abstract ideas, physical phenomena, and laws of nature are not eligible for patenting, methods and products employing abstract ideas, physical phenomena, and laws of nature to perform a real-world function may well be. In evaluating whether a claim meets the requirements of [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#), the claim must be considered as a whole to determine whether it is for a particular application of an abstract idea, physical phenomenon, or law of nature, and not for the abstract idea, physical phenomenon, or law of nature itself. *Diehr*, 450 U.S. at 188, 209 USPQ at 7.

In addition to the terms laws of nature, physical phenomena, and abstract ideas, judicially recognized exceptions have been described using various other terms, including natural phenomena, scientific principles, systems that depend on human intelligence alone, disembodied concepts, mental processes and disembodied mathematical algorithms and formulas, for example. The exceptions reflect the courts’ view that the basic tools of scientific and technological work are not patentable.

The claimed subject matter must not be wholly directed to a judicially recognized exception. If it is, the claim is not eligible for patent protection and should be rejected under [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#). However, a claim that is limited to a particular practical application of a judicially recognized exception is eligible for patent protection. A “practical application” relates to how a judicially recognized exception is applied in a real world product or a process, and not merely to the result achieved by the invention. When subject matter has been reduced to a particular practical application having a real world use, the claimed practical application is evidence that the subject matter is not abstract (e.g., not purely mental) and does not encompass substantially all uses (preemption) of a law of nature or a physical phenomenon. See, e.g., *Ultramercial v. Hulu*, 657 F.3d 1323, 1329, 100 USPQ2d 1140, 1145 (Fed. Cir. 2011) (stating that the patent “does not claim a mathematical algorithm, a series of purely mental steps, or any similarly abstract concept. It claims a particular method . . . a practical application of the general concept.”).

A. Practical Application of Machines, Manufactures, and Compositions of Matter (Products)

If the claimed product falls within one of the three product categories of invention and does not recite judicially excepted subject matter, e.g., a law of nature, a physical phenomenon, or an abstract idea, it qualifies as eligible subject matter. If a judicial exception is recited in the claim, it must be determined if the judicially excepted subject matter has been practically applied in the product.

Eligible machines, manufactures, and compositions of matter are non-naturally occurring products typically formed of tangible elements or parts that embody a particular or specific, tangible practical application of the invention. Thus, for these product categories, a particular practical application is often self-evident based on the claim limitations that define the tangible embodiment. This is because an idea that is tangibly applied to a structure is no longer abstract, and a law of nature or physical phenomenon that is practically applied to a structure is limited to that particular application of the concept. For example, a cup is the tangible application of the abstract idea of containing a liquid and is one limited embodiment of that idea (which is no longer abstract). As another example, a magnetic door latch is the tangible application of the concept of magnetism and does not wholly embrace the concept of magnetism but, rather, is one limited application of the concept.

A claim that includes terms that imply that the invention is directed to a product, for instance by reciting “a machine comprising...”, but fails to include tangible limitations in accordance with its broadest reasonable interpretation is not limited to a practical application, but rather wholly embraces or encompasses the concept upon which the invention is based. This is impermissible as such claim coverage would extend to every way of applying the abstract idea, law of nature or physical phenomenon.

A claim that includes judicially excepted subject matter and whose broadest reasonable interpretation is directed to a man-made tangible embodiment (i.e., structure) with a real world use is limited to a practical application (the subject matter has been practically applied). The reason is that the claim as a whole must be evaluated for eligibility in the same manner that a claim as a whole is evaluated for patentability under [35 U.S.C. 102 \(mpep-9015-appx-l.html#d0e302383\)](#), [103 \(mpep-9015-appx-l.html#d0e302450\)](#) and [112 \(mpep-9015-appx-l.html#d0e302824\)](#).

Once a practical application has been established, the limited occurrence of preemption must be evaluated to determine whether the claim impermissibly covers substantially all practical applications of the judicially excepted subject matter. If so, the claim is not patent-eligible. If the claim covers only a particular practical application of the judicially excepted subject matter, it is patent eligible.

The following examples show the difference between a tangible embodiment that is evidence of a particular practical application and an abstract concept that has no practical application.

- (a) A claim that is directed to a machine comprising a plurality of structural elements that work together in a defined combination based on a mathematical relationship, such as a series of gears, pulleys and belts, possesses structural limitations that show that it is a tangible embodiment. providing evidence that the mathematical relationship has been applied (a practical application). Additionally, that tangible embodiment is limited by the claimed structure and would not cover all substantial practical uses of the mathematical relationship. The claim would be eligible for patent protection.
- (b) On the other hand, a claim that is directed to a machine ("What is claimed is a machine that operates in accordance with $F=ma$.")) and includes no tangible structural elements under the broadest reasonable interpretation, covers the operating principle based on a mathematical relationship with no limits on the claim scope. Thus, as no tangible embodiment is claimed, there would be no evidence of a practical application. The claim would wholly embrace the mathematical concept of $F=ma$ and would not be eligible subject matter.
- (c) As another example, a claim to a non-transitory, tangible computer readable storage medium *per se* that possesses structural limitations under the broadest reasonable interpretation standard to qualify as a manufacture would be patent-eligible subject matter. Adding additional claim limitations to the medium, such as executable instructions or stored data, to such a statutory eligible claim would not render the medium non-statutory, so long as the claim as a whole has a real world use and the medium does not cover substantially all practical uses of a judicial exception. The claim as a whole remains a tangible embodiment and qualifies as a manufacture. As explained above, the additional claim limitations would be evaluated in terms of whether they distinguish over the prior art.

B. Practical Application of Processes (Methods)

The Supreme Court in *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218, 95 USPQ2d 1001 (2010), clarified the requirements for a claim to be a statutory process. Not every claimed method qualifies as a statutory process. A process claim, to be statutory under [35 U.S.C. 101 \(mpep-9015-appx-1.html#d0e302376\)](#), must be limited to a particular practical application. This ensures that the process is not simply claiming an abstract idea, or substantially all practical uses of (preempting) a law of nature, or a physical phenomenon. See [MPEP § 2106.01 \(s2106.html#d0e198001\)](#) for further guidance regarding subject matter eligibility determinations during examination of process claims that involve laws of nature/natural correlations.

A claim that attempts to patent an abstract idea is ineligible subject matter under [35 U.S.C. 101 \(mpep-9015-appx-1.html#d0e302376\)](#). See *Bilski*, 561 U.S. at ___, 130 S. Ct. at 3230, 95 USPQ2d at 1009 ("[A]ll members of the Court agree that the patent application at issue here falls outside of § 101 because it claims an abstract idea."). The abstract idea exception has deep roots in the Supreme Court's jurisprudence. See *Bilski*, 561 U.S. at ___, 130 S. Ct. at 3225, 95 USPQ2d at 1006 (citing *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 174–175 (1853)).

Bilski reaffirmed Diehr's holding that "while an abstract idea, law of nature, or mathematical formula could not be patented, 'an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.'" See *Bilski*, 561 U.S. at ___, 130 S. Ct. at 3230, 95 USPQ2d at 1010 (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)) (emphasis in original). The recitation of some structure, such as a machine, or the recitation of some transformative component will in most cases limit the claim to such an application. However, not all such recitations necessarily save the claim: "Flook established that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable." See *Bilski*, 561 U.S. at ___, 130 S. Ct. at 3231, 95 USPQ2d at 1010. Moreover, the fact that the steps of a claim might occur in the "real world" does not necessarily save it from a [35 U.S.C. 101 \(mpep-9015-appx-1.html#d0e302376\)](#) rejection. Thus, the *Bilski* claims were said to be drawn to an "abstract idea" despite the fact that they included steps drawn to initiating transactions. The "abstractness" is in the sense that there are no limitations as to the mechanism for entering into the transactions.

Consistent with the foregoing, *Bilski* holds that the following claim is abstract:

1. 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.

Specifically, the Court explains:

The concept of hedging, described in claim 1 and reduced to a mathematical formula in claim 4, is an unpatentable abstract idea, just like the algorithms at issue in *Benson* and *Flook*. Allowing petitioners to patent risk hedging would preempt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.

Bilski also held that the additional, narrowing, limitations in the dependent claims were mere field of use limitations or insignificant postsolution components, and that adding these limitations did not make the claims patent-eligible. Claims 1–9 in *Bilski* are examples of claims that run afoul of the abstract idea exception. The day after deciding *Bilski*, the Supreme Court denied certiorari in *Ferguson v. Kappos*, U.S. Supreme Court No. 09–1501, while granting, vacating, and remanding two other Federal Circuit [35 U.S.C. 101 \(mpep-9015-appx-1.html#d0e302376\)](#) cases. The denial of certiorari left intact the rejection of all of Ferguson's claims. Although the Federal Circuit had applied the machine-or-transformation test to reject Ferguson's process claims, the Supreme Court's disposition of *Ferguson* makes it likely that the Ferguson claims also run afoul of the abstract idea exception. A representative Ferguson claim is:

1. A method of marketing a product, comprising:

- Developing a shared marketing force, said shared marketing force including at least marketing channels, which enable marketing a number of related products;
- Using said shared marketing force to market a plurality of different products that are made by a plurality of different autonomous producing company [sic], so that different autonomous companies, having different ownerships, respectively produce said related products;
- Obtaining a share of total profits from each of said plurality of different autonomous producing companies in return for said using; and
- Obtaining an exclusive right to market each of said plurality of products in return for said using.

The following guidance presents factors that are to be considered when evaluating patent-eligibility of method claims. The factors include inquiries from the machine-or-transformation test, which remains a useful investigative tool, and inquiries gleaned from Supreme Court precedent. See *In re Bilski*, 545 F.3d 943, 954, 88 USPQ2d 1385, 1391 (Fed. Cir. 2009) (stating that “[a] claimed process is surely patent-eligible under [§ 101 \(mpep-9015-appx-1.html#d0e302376\)](#) if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”); and *Bilski*, 561 U.S. at ___, 130 S. Ct. at 3227, 95 USPQ2d at 1007 (stating, “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 \(mpep-9015-appx-1.html#d0e302376\)](#).”). The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible “process.”).

While the Supreme Court in *Bilski* did not set forth detailed guidance, there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a method claim is directed to an abstract idea. The following factors are intended to be useful examples and are not intended to be exclusive or limiting. It is recognized that new factors may be developed, particularly for emerging technologies. It is anticipated that the factors will be modified and changed to take into account developments in precedential case law and to accommodate prosecution issues that may arise in implementing this new practice.

Where the claim is written in the form of a method and is potentially a patentable process, as defined in [35 U.S.C. 100\(b\) \(mpep-9015-appx-1.html#d0e302350\)](#), the claim is patent-eligible so long as it is not disqualified as one of the exceptions to [35 U.S.C. 101 \(mpep-9015-appx-1.html#d0e302376\)](#)’s broad patent-eligibility principles; i.e., laws of nature, physical phenomena, and abstract ideas.

Taking into account the following factors, the examiner should determine whether the claimed invention, viewed as a whole, is disqualified as being a claim to an abstract idea. Relevant factors—both those in favor of patent-eligibility and those against such a finding—should be weighed in making the determination. Factors that weigh in favor of patent-eligibility satisfy the criteria of the machine-or-transformation test or provide evidence that the abstract idea has been practically applied. Factors that weigh against patent-eligibility neither satisfy the criteria of the machine-or-transformation test nor provide evidence that the abstract idea has been practically applied. Each case will present different factors, and it is likely that only some of the factors will be present in each application. It would be improper to make a conclusion based on one factor while ignoring other factors.

With respect to the factors listed below, a “field-of-use” limitation does not impose actual boundaries on the scope of the claimed invention. A field-of-use limitation merely indicates that the method is for use in a particular environment, such as “for use with a machine” or “for transforming an article”, which would not require that the machine implement the method or that the steps of the method cause the article to transform. A field-of-use limitation does not impose a meaningful limit on the claimed invention. Insignificant “extra-solution” activity means activity that is not central to the purpose of the method invented by the applicant. For example, gathering data to use in the method when all applications of the method would require some form of data gathering would not impose a meaningful limit on the claim.

1. Factors To Be Considered in an Abstract Idea Determination of a Method Claim

(a) Whether the method involves or is executed by a particular machine or apparatus

“The machine-or-transformation test is a useful and important clue, and investigative tool, for determining whether some claimed inventions are processes under [§ 101 \(mpep-9015-appx-1.html#d0e302376\)](#).” *Bilski v. Kappos*, 561 U.S. ___, ___, 130 S. Ct. 3218, 3227, 95 USPQ2d 1001, 1007 (2010). If so, the claims are less likely to be drawn to an abstract idea; if not, they are more likely to be so drawn. With respect to these factors, a “machine” is a concrete thing, consisting of parts, or of certain devices and combination of devices. This includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result. This definition is interpreted broadly to include electrical, electronic, optical, acoustic, and other such devices that accomplish a function to achieve a certain result. An “apparatus” does not have a significantly different meaning from a machine and can include a machine or group of machines or a totality of means by which a designated function or specific task is executed.

Where a machine or apparatus is recited or inherent in a patent claim, the following factors are relevant:

(a) The particularity or generality of the elements of the machine or apparatus; i.e., the degree to which the machine in the claim can be specifically identified (not any and all machines). Incorporation of a particular machine or apparatus into the claimed method steps weighs toward eligibility.

For computer implemented processes, the “machine” is often disclosed as a general purpose computer. In these cases, the general purpose computer may be sufficiently “particular” when programmed to perform the process steps. Such programming creates a new machine because a general purpose computer, in effect, becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software. *In re Alappat*, 33 F.3d 1526, 1545, 31 USPQ 1545, 1558 (Fed. Cir. 1994); see also *Ultramercial v. Hulu*, 657 F.3d 1323, 1329, 100 USPQ2d 1140, 1145 (Fed. Cir. 2011) (stating “a programmed computer contains circuitry unique to that computer”). However, “adding a ‘computer-aided’ limitation to a claim covering an abstract concept, without more, is insufficient to render [a] patent claim eligible” where the claims “are silent as to how a computer aids the method, the extent to which a computer aids the method, or the significance of a computer to the performance of the method.” *DealerTrack v. Huber*, 674 F.3d 1315, 1333, 101 USPQ2d 1325, 1339-40 (Fed. Cir. 2012). To qualify as a particular machine under the test, the claim must clearly convey that the computer is programmed to perform the steps of the method because such programming, in effect, creates a special purpose computer limited to the use of the particularly

claimed combination of elements (i.e., the programmed instructions) performing the particularly claimed combination of functions. If the claim is so abstract and sweeping that performing the process as claimed would cover substantially all practical applications of a judicial exception, such as a mathematical algorithm, the claim would not satisfy the test as the machine would not be sufficiently particular.

(b) Whether the machine or apparatus implements the steps of the method. Integral use of a machine or apparatus to achieve performance of the method weighs toward eligibility, as compared to where the machine or apparatus is merely an object on which the method operates, which weighs against eligibility. See *Cybersource v. Retail Decisions*, 654 F.3d 1366, 99 USPQ2d 1960 (Fed. Cir. 2011) (“We are not persuaded by the appellant’s argument that claimed method is tied to a particular machine because it ‘would not be necessary or possible without the Internet.’ . . . Regardless of whether “the Internet” can be viewed as a machine, it is clear that the Internet cannot perform the fraud detection steps of the claimed method”).

(c) Whether its involvement is extrasolution activity or a field-of-use, i.e., the extent to which (or how) the machine or apparatus imposes meaningful limits on the execution of the claimed method steps. Use of a machine or apparatus that contributes only nominally or insignificantly to the execution of the claimed method (e.g., in a data gathering step or in a field-of-use limitation) would weigh against eligibility. See *Bilski*, 561 U.S. at ___138 S. Ct. at 3230, 95 USPQ2d at 1009 (citing *Parker v. Flook*, 437 U.S. 584, 590, 198 USPQ 193, 197 (1978)), and *Cybersource v. Retail Decisions*, 654 F.3d 1366, 1375, 99 USPQ2d 1690, 1694 (Fed. Cir. 2011)(citations omitted) (“[N]othing in claim 3 requires an infringer to use the Internet to obtain that data . . . [t]he Internet is merely described as the source of the data. We have held that mere “[data-gathering] step[s] cannot make an otherwise nonstatutory claim statutory.” 654 F.3d at 1375, 99 USPQ2d at 1694 (citation omitted).)

(b) Whether performance of the claimed method results in or otherwise involves a transformation of a particular article

“[T]ransformation and reduction of an article ‘to a different state or thing’ is the clue to patentability of a process claim that does not include particular machines.” *Bilski v. Kappos*, 561 U.S. ___, ___, 130 S. Ct. 3218, 3227, 95 USPQ2d 1001, 1007 (2010) (quoting *Gottschalk v. Benson*, 409 U.S. 63, 70, 175 USPQ 673, 676 (1972)). If such a transformation exists, the claims are less likely to be drawn to an abstract idea; if not, they are more likely to be so drawn.

An “article” includes a physical object or substance. The physical object or substance must be particular, meaning it can be specifically identified. An article can also be electronic data that represents a physical object or substance. For the test, the data should be more than an abstract value. Data can be specifically identified by indicating what the data represents, the particular type or nature of the data, and/or how or from where the data was obtained.

“Transformation” of an article means that the “article” has changed to a different state or thing. Changing to a different state or thing usually means more than simply using an article or changing the location of an article. A new or different function or use can be evidence that an article has been transformed. Manufactures and compositions of matter are the result of transforming raw materials into something new with a different function or use. Purely mental processes in which thoughts or human based actions are “changed” are not considered an eligible transformation. For data, mere “manipulation of basic mathematical constructs [i.e.] the paradigmatic ‘abstract idea’,” has not been deemed a transformation. *Cybersource v. Retail Decisions*, 654 F.3d 1366, 1372 n.2, 99 USPQ2d 1690, 1695 n.2 (Fed. Cir. 2011)(quoting *In re Warmerdam*, 33 F.3d 1354, 1355, 1360 (Fed. Cir. 1994)). However, transformation of electronic data has been found when the nature of the data has been changed such that it has a different function or is suitable for a different use. *In re Bilski*, 545 F.3d 943, 962-63, 88 USPQ2d 1385, 1399 (Fed. Cir. 2009) (*aff’d sub nom Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218, 95 USPQ2d 1001 (2010)).

Where a transformation occurs, the following factors are relevant:

(a) The particularity or generality of the transformation. The Supreme Court has stated that an invention comprising a process of “tanning, dyeing, making waterproof cloth, vulcanizing India rubber [or] smelting ores’ . . . are instances . . . where the use of chemical substances or physical acts, such as temperature control, changes articles or materials [in such a manner that is] sufficiently definite to confine the patent monopoly within rather definite bounds.” *Gottschalk v. Benson*, 409 U.S. 63, 70, 175 USPQ 673, 676 (1972) (discussing *Coming v. Burden*, 15 How.(56 U.S.) 252, 267-68). A more particular transformation would weigh in favor of eligibility.

(b) The degree to which the recited article is particular; i.e., can be specifically identified (not any and all articles). A transformation applied to a generically recited article would weigh against eligibility.

(c) The nature of the transformation in terms of the type or extent of change in state or thing, for instance by having a different function or use, which would weigh toward eligibility, compared to merely having a different location, which would weigh against eligibility.

(d) The nature of the article transformed, i.e., whether it is an object or substance, weighing toward eligibility, compared to a concept such as a contractual obligation or mental judgment, which would weigh against eligibility.

(e) Whether its involvement is extrasolution activity or a field-of-use, i.e., the extent to which (or how) the transformation imposes meaningful limits on the execution of the claimed method steps. A transformation that contributes only nominally or insignificantly to the execution of the claimed method (e.g., in a data gathering step or in a field-of-use limitation) would weigh against eligibility.

(c) Whether performance of the claimed method involves an application of a law of nature, even in the absence of a particular machine, apparatus, or transformation

An application of a law of nature may represent patent-eligible subject matter even in the absence of a particular machine, apparatus, or transformation. See, e.g., *Bilski v. Kappos*, 561 U.S. ___, ___, 130 S. Ct. 3218, 3227, 95 USPQ2d 1001, 1007 (2010) (stating that the Court had previously “explicitly declined to ‘hold that no process patent could ever qualify if it did not meet [machine or transformation] requirements.’”) (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67, 175 USPQ 673, 676 (1972)). If such an application exists, the claims are less likely to be drawn to an abstract idea; if not, they are more likely to be so drawn. See [MPEP § 2106.01 \(s2106.html#d0e198001\)](http://www.uspto.gov/web/offices/pac/mpeps/2106.html) for further guidance regarding subject matter eligibility determinations during examination of process claims that involve laws of nature/natural correlations.

Where such an application is present, the following factors are relevant:

(a) The particularity or generality of the application. Application of a law of nature having broad applicability across many fields of endeavor weighs against eligibility, such as where the claim generically recites an effect of the law of nature or claims every mode of accomplishing that effect, such that the claim would monopolize a natural force or patent a scientific fact. See *O'Reilly v. Morse*, 56 U.S. 62 (1853)(finding unpatentable a claim for "the use of electromagnetism for transmitting signals at a distance"); *The Telephone Cases*, 126 U.S. 1, 209 (1888)(discussing a method of "transmitting vocal or other sound telegraphically ... by causing electrical undulations, similar in form to the vibrations of the air accompanying the said vocal or other sounds," stating "[Bell] had detected a secret of nature . . . [H]e proceeded promptly to patent, not only a particular method and apparatus for availing of that law, but also the right to avail of that law by any means whatever. Thus considered he has been able to monopolize a natural force, and patent a scientific fact.").

(b) Whether the claimed method recites an application of a law of nature solely involving subjective determinations; e.g., ways to think about the law of nature. Application of a law of nature to a particular way of thinking about, or reacting to, a law of nature would weigh against eligibility. See *The Telephone Cases*, 126 U.S. at 210 (stating "[counsel for defendant] argued, that in all the cases upholding a claim for a process, the process was one capable of being sensually perceived, verified and proved by oath – not as a matter of opinion, but as a matter of fact."). *Id.* at 211 (discussing *Tilghman v. Proctor*, 102 U.S. 707 (1880) ("[t]here was a process, all of which lay within ordinary means of observation and verification.")).

(c) Whether its involvement is extrasolution activity or a field-of-use, i.e., the extent to which (or how) the application imposes meaningful limits on the execution of the claimed method steps. An application of the law of nature that contributes only nominally or insignificantly to the execution of the claimed method (e.g., in a data gathering step or in a field-of-use limitation) would weigh against eligibility.

(d) Whether a general concept (which could also be recognized in such terms as a principle, theory, plan or scheme) is involved in executing the steps of the method

The presence of such a general concept can be a clue that the claim is drawn to an abstract idea. Where a general concept is present, the following factors are relevant:

(a) The extent to which use of the concept, as expressed in the method, would preempt its use in other fields; i.e., that the claim would effectively grant a monopoly over the concept. *Bilski v. Kappos*, 561 U.S. ___, ___, 130 S. Ct. 3218, 3231, 95 USPQ2d 1001, 1010 (2010).

(b) The extent to which the claim is so abstract and sweeping as to cover both known and unknown uses of the concept, and be performed through any existing or future-devised machinery, or even without any apparatus. *Gottschalk v. Benson*, 409 U.S. 63, 68, 175 USPQ 673, 676 (1972) (stating "[h]ere the process' claim is so abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary conversion. The end use may (1) vary from the operation of a train to verification of drivers' licenses to researching the law books for precedents and (2) be performed through any existing machinery or future-devised machinery or without any apparatus").

(c) The extent to which the claim would effectively cover all possible solutions to a particular problem; i.e., that the claim is a statement of the problem versus a description of a particular solution to the problem. See *The Telephone Cases*, 126 U.S. 1, 161-162 (1888) (discussing *Tilghman v. Proctor*, 102 U.S. 707 (1880) ("The claim of the patent [in *Tilghman*] is not for a mere principle.' . . . In that case there was a problem. Find a way, if you can, to combine each atom of water with an atom of acid. If you can do that, then you can reach this important result of resolving the neutral fats into glycerine and acids. And *Tilghman's* solution of it was: Heat the water under such pressure that the water shall not pass into steam. This was his process; and he claimed, and the court justly allowed, great latitude in its application.")).

(d) Whether the concept is disembodied or whether it is instantiated; i.e., implemented, in some tangible way. A concept that is well-instantiated weighs in favor of eligibility.

See, e.g., *Bilski*, 561 U.S. at ___, 138 S. Ct. at 3230, 95 USPQ2d at 1010 (stating that the Court in *Diehr* "concluded that because the claim was not 'an attempt to patent a mathematical formula, but rather [was] an industrial process for the molding of rubber products,' it fell within § 101's (mpep-9015-appx-I.html#d0e302376) patentable subject matter." (citing *Diehr*, 450 U.S. at 192-93, 209 USPQ at 10)). Accord *Research Corp. Technologies v. Microsoft Corp.*, 627 F.3d 859, 868-69, 97 USPQ2d 1274, 1281 (Fed. Cir. 2010) (stating that the claims here "do not seek to patent a mathematical formula" but rather a process of halftoning in computer applications, presenting "functional and palpable applications in the field of computer technology" such that applicant's claimed invention requires instantiation (in some claims) through "'a 'high contrast film,' 'a film printer,' 'a memory,' and 'printer and display devices'"); *Ulramercial v. Hulu*, 657 F.3d 1323, 1328, 100 USPQ2d 1140, 1144(Fed. Cir. 2011) (stating that the patent "does not simply claim the age-old idea that advertising can serve as currency, [but instead] a practical application of this idea.").

A concept that is not well-instantiated weighs against eligibility. See *DealerTrack v. Huber*, ___ F.3d ___, 101 USPQ2d 1325 (Fed. Cir. 2012) where in the court stated:

The claims are silent as to how a computer aids the method, the extent to which a computer aids the method, or the significance of a computer to the performance of the method. The undefined phrase "computer-aided" is no less abstract than the idea of a clearinghouse itself. Because the computer here "can be programmed to perform very different tasks in very different ways," it does not "play a significant part in permitting the claimed method to be performed." Simply adding a "computer aided" limitation to a claim covering an abstract concept, without more, is insufficient to render the claim patent eligible. . . . "In order for the addition of a machine to impose a meaningful limit on the scope of a claim, it must play a significant part in permitting the claimed method to be performed, rather than function solely as an obvious mechanism for permitting a solution to be achieved more quickly, i.e., through the utilization of a computer for performing calculations."

674 F.3d at 1315, 1333, 101 USPQ2d at 1339-40 (citations omitted). Furthermore, limiting an abstract idea to one field of use or adding token postsolution components does not make the concept patentable.

(e) The mechanism(s) by which the steps are implemented; e.g., whether the performance of the process is observable and

verifiable rather than subjective or imperceptible. Steps that are observable and verifiable weigh in favor of eligibility. *The Telephone Cases*, 126 U.S. at 211 (discussing *Tilghman v. Proctor*, 102 U.S. 707 (1880) (“[t]here was a process, all of which lay within ordinary means of observation and verification”).

(f) Examples of general concepts include, but are not limited to:

- Basic economic practices or theories (e.g., hedging, insurance, financial transactions, marketing);
- Basic legal theories (e.g., contracts, dispute resolution, rules of law);
- Mathematical concepts (e.g., algorithms, spatial relationships, geometry);
- Mental activity (e.g., forming a judgment, observation, evaluation, or opinion);
- Interpersonal interactions or relationships (e.g., conversing, dating);
- Teaching concepts (e.g., memorization, repetition);
- Human behavior (e.g., exercising, wearing clothing, following rules or instructions);
- Instructing “how business should be conducted.”

See, e.g., *Bilski*, 138 S. Ct. at 3231 (stating “[t]he concept of hedging, described in claim 1 and reduced to a mathematical formula in claim 4, is an unpatentable abstract idea.”); *In re Ferguson*, 558 F.3d 1359, 90 USPQ2d 1035 (2009) (cert. denied *Ferguson v. PTO*, June 29, 2010)(finding ineligible “methods . . . directed to organizing business or legal relationships in the structuring of a sales force (or marketing company);” *Benson*, 409 U.S. at 67, 175 USPQ at 675 (stating “mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”); *Bilski*, 130 S. Ct. at 3231 (quoting *Le Roy v. Tatham*, 14 How. (55 U.S.) 156, 175 (“[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”). See also *Bilski*, 130 S. Ct. at 3259 (Breyer, J. concurring).

2. Making the Determination of Eligibility

Each of the factors relevant to the particular patent application should be weighed to determine whether the method is claiming an abstract idea by covering a general concept, or combination of concepts, or whether the method is limited to a particular practical application of the concept. The presence or absence of a single factor will not be determinative as the relevant factors need to be considered and weighed to make a proper determination as to whether the claim as a whole is drawn to an abstract idea such that the claim would effectively grant a monopoly over an abstract idea and be ineligible for patent protection.

If the factors indicate that the method claim is not merely covering an abstract idea, the claim is eligible for patent protection under [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#) and must be further evaluated for patentability under all of the statutory requirements, including utility and double patenting ([35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#)); novelty ([35 U.S.C. 102 \(mpep-9015-appx-l.html#d0e302383\)](#)); non-obviousness ([35 U.S.C. 103 \(mpep-9015-appx-l.html#d0e302450\)](#)); and definiteness and adequate description, enablement, and best mode ([35 U.S.C. 112 \(mpep-9015-appx-l.html#d0e302824\)](#)). [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#) is merely a coarse filter and thus a determination of eligibility under [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#) is only a threshold question for patentability. [35 U.S.C. 102 \(mpep-9015-appx-l.html#d0e302383\)](#), [103 \(mpep-9015-appx-l.html#d0e302450\)](#), and [112 \(mpep-9015-appx-l.html#d0e302824\)](#) are typically the primary tools for evaluating patentability unless the claim is truly abstract, see, e.g., *Bilski v. Kappos*, 561 U.S. ___, ___, 130 S. Ct. 3218, 3229, 95 USPQ2d 1001, 1008 (2010). (“[S]ome business method patents raise special problems in terms of vagueness and suspect validity.”).

If the factors indicate that the method claim is attempting to cover an abstract idea, the examiner will reject the claim under [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#), providing clear rationale supporting the determination that an abstract idea has been claimed, such that the examiner establishes a *prima facie* case of patent-ineligibility. The conclusion made by the examiner must be based on the evidence as a whole. In making a rejection or if presenting reasons for allowance when appropriate, the examiner should specifically point out the factors that are relied upon in making the determination. If a claim is rejected under [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#) on the basis that it is drawn to an abstract idea, the applicant then has the opportunity to explain why the claimed method is not drawn to an abstract idea. Specifically identifying the factors used in the analysis will allow the applicant to make specific arguments in response to the rejection if the applicant believes that the conclusion that the claim is directed to an abstract idea is in error.

III. Establish on the Record a *Prima Facie* Case

USPTO personnel should review the totality of the evidence (e.g., the specification, claims, relevant prior art) before reaching a conclusion with regard to whether the claimed invention sets forth patent eligible subject matter. USPTO personnel must weigh the determinations made above to reach a conclusion as to whether it is more likely than not that the claimed invention as a whole either falls outside of one of the enumerated statutory classes or within one of the exceptions to statutory subject matter. “The examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). If the record as a whole suggests that it is more likely than not that the claimed invention would be considered a practical application of an abstract idea, physical phenomenon, or law of nature, then USPTO personnel should not reject the claim.

After USPTO personnel identify and explain in the record the reasons why a claim is for an abstract idea, physical phenomenon, or law of nature with no practical application, then the burden shifts to the applicant to either amend the claim or make a showing of why the claim is eligible for patent protection. See, e.g., *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995); see generally [MPEP § 2107 \(s2107.html#d0e198469\)](#) (Utility Guidelines).

Under the principles of compact prosecution, each claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application, even if one or more claims are found to be deficient with respect to the patent-eligibility requirement of [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#). Thus, Office personnel should state all non-cumulative reasons and bases for rejecting claims in the first Office action.

2106.01 Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature [R-11.2013]

I. SUMMARY

The following guidance is intended for use in subject matter eligibility determinations during examination of process claims that involve laws of nature/natural correlations, such as the claims in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S.Ct. 1289, 101 USPQ2d 1961 (2012) (*Mayo*). Process claims that are directed to abstract ideas, such as the claims in *Dilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218, 95 USPQ2d 1001 (2010), should continue to be examined using the guidance set forth in [MPEP § 2106 \(s2106.html#d0e197244\)](#).

The guidance set forth in this section should be followed for examination of process claims in which a law of nature, a natural phenomenon, or a naturally occurring relation or correlation (collectively referred to as a natural principle in the guidance) is a limiting element or step. In summary, process claims having a natural principle as a limiting element or step should be evaluated by determining whether the claim includes additional elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself. If the claim as a whole satisfies this inquiry, the claim is directed to patent-eligible subject matter. If the claim as a whole does not satisfy this inquiry, it should be rejected under [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#) as being directed to non-statutory subject matter.

II. ESSENTIAL INQUIRIES FOR SUBJECT MATTER ELIGIBILITY UNDER 35 U.S.C. 101

After determining what applicant invented and establishing the broadest reasonable interpretation of the claimed invention, conduct the following three inquiries on the claim as a whole to determine whether the claim is drawn to patent-eligible subject matter. Further details regarding each inquiry are provided below.

- **1. Is the claimed invention directed to a process, defined as an act, or a series of acts or steps?**
If no, this analysis is not applicable. For product claims see [MPEP § 2106 \(s2106.html#d0e197244\)](#). If yes, proceed to Inquiry 2.
- **2. Does the claim focus on use of a law of nature, a natural phenomenon, or naturally occurring relation or correlation (collectively referred to as a natural principle herein)? (Is the natural principle a limiting feature of the claim?)**
If no, this analysis is complete, and the claim should be analyzed to determine if an abstract idea is claimed (see [MPEP § 2106 \(s2106.html#d0e197244\)](#)). If yes, proceed to Inquiry 3.
- **3. Does the claim include additional elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself? (Is it more than a law of nature plus the general instruction to simply “apply it”?)**
If no, the claim is not patent-eligible and should be rejected. If yes, the claim is patent-eligible, and the analysis is complete.

III. DETAILED GUIDANCE FOR USING THE INQUIRIES

A. Determining What Applicant Invented and the Broadest Reasonable Interpretation

Review the entire specification and claims to determine what applicant believes that he or she invented. Then review the claims to determine the boundaries of patent protection sought by the applicant and to understand how the claims relate to and define what the applicant has indicated is the invention.

Claim analysis begins by identifying and evaluating each claim limitation and then considering the claim as a whole. It is improper to dissect a claimed invention into discrete elements and then evaluate the elements in isolation because it is the combination of claim limitations functioning together that establish the boundaries of the invention and limit its scope.

Establish the broadest reasonable interpretation of the claims when read in light of the specification and from the view of one of ordinary skill in the art. This same interpretation must be used to evaluate the compliance with each statutory requirement. See [MPEP § 2111 \(s2111.html#d0e200352\)](#) and [§ 2173 \(s2173.html#d0e217564\)](#) *et seq.* for further details of claim construction and compliance with [35 U.S.C. 112\(b\) \(mpep-9015-appx-l.html#al_d1d85b_2ae65_215\)](#) and [pre-AIA 35 U.S.C. 112 \(mpep-9015-appx-l.html#d0e302824\)](#), second paragraph, respectively.

B. INQUIRY 1: Process

Under this analysis, the claim must be drawn to a process. A process is defined as an act, or a series of acts or steps. Process claims are sometimes called method claims.

C. INQUIRY 2: Natural Principle

Does the claim focus on use of a natural principle, i.e., a law of nature, a natural phenomenon, or naturally occurring relation or correlation? (Is the natural principle a limiting feature of the claim?)

A natural principle is the handiwork of nature and occurs without the hand of man. For example, the disinfecting property of sunlight is a natural principle. The relationship between blood glucose levels and diabetes is a natural principle. A correlation that occurs naturally when a man-made product, such as a drug, interacts with a naturally occurring substance, such as blood, is also considered a natural principle because, while it takes a human action to trigger a manifestation of the correlation, the correlation exists in principle apart from any human action. These are illustrative examples and are not intended to be limiting or exclusive.

For this analysis, a claim focuses on a natural principle when the natural principle is a limiting element or step. In that case, the claim must be analyzed (in Inquiry 3) to ensure that the claim is directed to a practical application of the natural principle that amounts to substantially more than the natural principle itself. So, for instance, a claim that recites a correlation used to make a

diagnosis focuses on a natural principle and would require further analysis under Inquiry 3.

If a natural principle is not a limitation of the claim, the claim does not focus on the use of a natural principle and requires no further analysis under this procedure. If the claim focuses on an abstract idea, such as steps that can be performed entirely in one's mind, methods of controlling human activity, or mere plans for performing an action, refer to [MPEP § 2106 \(s2106.html#d0e197244\)](#) to evaluate eligibility.

D. INQUIRY 3: Practical Application and Preemption

Does the claim include additional elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself? (Is it more than a law of nature plus the general instruction to simply “apply it”?)

A claim that focuses on use of a natural principle must also include additional elements or steps to show that the inventor has practically applied, or added something significant to, the natural principle itself. See *Mayo*, 566 U.S. at ___, 132 S.Ct. at 1294, 101 USPQ2d at 1966. To show integration, the additional elements or steps must relate to the natural principle in a significant way to impose a meaningful limit on the claim scope. The analysis turns on whether the claim has added enough to show a practical application. See *id.* at 1968. In other words, the claim cannot cover the natural principle itself such that it is effectively standing alone. A bare statement of a naturally occurring correlation, albeit a newly discovered natural correlation or very narrowly confined correlation, would fail this inquiry. See *id.* at 1965, 1971.

It is not necessary that every recited element or step integrate or relate to the natural principle as long as it is applied in some practical manner. However, there must be at least one additional element or step that applies, relies on or uses the natural principle so that the claim amounts to significantly more than the natural principle itself. Elements or steps that do not integrate the natural principle and are merely appended to it would not be sufficient. In other words, the additional elements or steps must not simply amount to insignificant extra-solution activity that imposes no meaningful limit on the performance of the claimed invention. See *id.* at 1966. For example, a claim to diagnosing an infection that recites the step of correlating the presence of a certain bacterium in a person's blood with a particular type of bacterial infection with the additional step of recording the diagnosis on a chart would not be eligible because the step of recording the diagnosis on the chart is extra-solution activity that is unrelated to the correlation and does not integrate the correlation into the invention.

Along with integration, the additional steps must be sufficient to ensure that the claim amounts to significantly more than the natural principle itself by including one or more elements or steps that limit the scope of the claim and do more than generally describe the natural principle with generalized instructions to “apply it.” See *id.* at 1965, 1968. The additional elements or steps must narrow the scope of the claim such that others are not foreclosed from using the natural principle (a basic tool of scientific and technological work) for future innovation. Elements or steps that are well-understood, purely conventional, and routinely taken by others in order to apply the natural principle, or that only limit the use to a particular technological environment (field-of-use), would not be sufficiently specific. See *id.* at 1968. A claim with steps that add something of significance to the natural laws themselves would be eligible because it would confine its reach to particular patent-eligible applications of those laws, such as a typical patent on a new drug (including associated method claims) or a new way of using an existing drug. See *id.* at 1971; see also [35 U.S.C. 100\(b\) \(mpep-9015-appx-l.html#d0e302350\)](#). In other words, the claim must be limited so that it does not preempt the natural principle being recited by covering every substantial practical application of that principle. The process must have additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. See *id.* at 1968.

A claim that would fail this inquiry includes, for example, a claim having a limitation that describes a law of nature and additional steps that must be taken in order to apply the law of nature by establishing the conditions under which the law of nature occurs such as a step of taking a sample recited at a high level of generality to test for a naturally occurring correlation. See *id.* at 1970. Adding steps to a natural biological process that only recite well-understood, routine, conventional activity previously engaged in by researchers in the field would not be sufficient. See *id.* at 1966, 1970. A combination of steps that amounts to nothing significantly more than an instruction to doctors to “apply” applicable natural laws when treating their patients would also not be sufficient. See *id.* at 1970.

Claims that do not include a natural principle as a limitation do not raise issues of subject matter eligibility under the law of nature exception. For example, a claim directed to simply administering a man-made drug that does not recite other steps or elements directed to use of a natural principle, such as a naturally occurring correlation, would be directed to eligible subject matter. Further, a claim that recites a novel drug or a new use of an existing drug, in combination with a natural principle, would be sufficiently specific to be eligible because the claim would amount to significantly more than the natural principle itself. However, a claim does not have to be novel or non-obvious to qualify as a subject matter eligible claim. Moreover, a claim that is deemed eligible is not necessarily patentable unless it also complies with the other statutory and non-statutory considerations for patentability under [35 U.S.C. 101 \(mpep-9015-appx-l.html#d0e302376\)](#) (utility and double patenting), [102 \(mpep-9015-appx-l.html#d0e302383\)](#), [103 \(mpep-9015-appx-l.html#d0e302450\)](#), [112 \(mpep-9015-appx-l.html#d0e302824\)](#), and non-statutory double patenting.

The weighing factors used in [MPEP § 2106 \(s2106.html#d0e197244\)](#) are useful tools for assisting in the evaluation. For convenience, these factors and how they may assist in the analysis are summarized below.

E. Relevant Factors Useful for Inquiry 3

The following factors can be used to analyze the additional features in the claim to determine whether the claim recites a patent-eligible practical application of a natural principle and assist in answering Inquiry 3 above. Many of these factors originate from past eligibility factors, including the ‘Machine-or-Transformation’ (M-or-T) test. However, satisfying the M-or-T factors does not ensure eligibility if the claim features that include a particular machine or transformation do not integrate the natural principle into the claimed invention to show that the natural principle is practically applied, and are not sufficient to ensure that the claim amounts to significantly more than the natural principle itself.

- Appending conventional steps, specified at a high level of generality, to a natural principle does not make the claim

- patent-eligible.
- Steps that amount to instructions that are well-understood, routine, conventional activity, previously engaged in by those in the field add nothing specific to the natural principle that would render it patent-eligible.
 - A claim that covers known and unknown uses of a natural principle and can be performed through any existing or future-devised machinery, or even without any apparatus, would lack features that are sufficient for eligibility.
 - A particular machine or transformation recited in more than general terms may be sufficient to limit the application to just one of several possible machines or just one of several possible changes in state, such that the claim does not cover every substantial practical application of a natural principle. This can be contrasted with only adding features that limit the application to a certain technological environment (e.g., for use in catalytic conversion systems), which would cover every substantial practical application in that field.
 - Additional limitations that are necessary for all practical applications of the natural principle, such that everyone practicing the natural principle would be required to perform those steps or every product embodying that natural principle would be required to include those features, would not be sufficient.
 - A particular machine or transformation recited in a claim can show how the natural principle is integrated into a practical application by describing the details of how that machine and its specific parts implement the natural principle (e.g., the parts of an internal combustion engine apply the concept of combustion to produce energy) or how the transformation relates to or implements the natural principle (e.g., using ionization in a manufacturing process).
 - A machine or transformation that is merely nominally, insignificantly, or tangentially related to the steps or elements, e.g., data gathering or data storage, would not show integration. For example, a machine that is simply incidental to execution of the method (using a computer as a counter balance weight and not as a processing device) rather than an object that implements the method or a transformation that involves only a change of position or location of an object rather than a change in state or thing does not show that these additional features integrate the natural principle into the invention as they are incidental to the claimed invention.
 - Complete absence of a machine-or-transformation in a claim signals the likelihood that the claim is directed to a natural principle and has not been instantiated (e.g., is disembodied or can be performed entirely in one's mind.)
 - A mere statement of a general concept (natural principle) would effectively monopolize that concept/principle and would be insufficient. This can be contrasted with a tangible implementation with elements or steps that are recited with specificity such that all substantial applications are not covered. Such specificity may be achieved with observable and verifiable steps, for example, rather than subjective or imperceptible steps.

IV. SAMPLE ANALYSIS

A. Sample Claim Drawn to a Patent-Eligible Practical Application - *Diamond v. Diehr*

1. 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 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.

The above claim was found to be a patent-eligible practical application in *Diamond v. Diehr*, 450 U.S. 175, 209 USPQ 1 (1981). Recently, the Supreme Court looked back to this claim as an example of a patent-eligible practical application as explained in the following excerpt from *Mayo*:

The Court pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it found the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole. Those steps included "installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time." [] It nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional. And so the patentees did not "seek to preempt the use of [the] equation," but sought "only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process." [] These other steps apparently added to the formula something that in terms of patent law's objectives had significance—they transformed the process into an inventive application of the formula. *Mayo*, 566 U.S. at ___, 132 S.Ct. at 1298-99, 101 USPQ2d at 1969 (emphasis added).

This claim would pass Inquiries 1-3 in the above analysis as it is a process that includes the Arrhenius equation as a limitation, with additional steps that integrate the Arrhenius equation into the process and are sufficient to narrow the scope of the claim so that others are not foreclosed from using the Arrhenius equation in different applications.

B. Sample Claim Drawn to Ineligible Subject Matter - *Mayo 566 U.S. at ___, 132 S.Ct. at 1295, 101 USPQ2d at 1966-67.*

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

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

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

The above claim was found to be ineligible in *Mayo*. The Supreme Court determined that the claim focused on use of a law of nature that was given weight during prosecution of the claim – specifically the relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. See *id.* 566 U.S. at ___, 132 S.Ct. at 1298, 101 USPQ2d at 1968-69. The Court analyzed the claim as follows:

The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws? We believe that the answer to this question is no. *Id.* 566 U.S. at ___, 132 S.Ct. at 1297, 101 USPQ2d at 1968.

The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities. *Id.* 566 U.S. at ___, 132 S.Ct. at 1298, 101 USPQ2d at 1968.

This claim would pass Inquiries 1-2 and fail Inquiry 3. It is a process claim that includes a natural principle that was construed as a limiting feature of a claim during prosecution - the natural principle being the naturally occurring relationships noted above, which are a consequence of the ways in which thiopurine compounds are metabolized by the body. The Court emphasized that while it takes a human action to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. See *id.* 566 U.S. at ___, 132 S.Ct. at 1297, 101 USPQ2d at 1967. The additional steps integrate the relationship into the process as the administering step involves the thiopurine drug, the determining step establishes the thiopurine drug level and the wherein clauses set forth the critical levels. The steps are not sufficient, however, to narrow the application such that others could still make use of the naturally occurring relationship in other practical applications. The claim essentially sets forth a law of nature with generalized instructions to apply it.

C. Making a Rejection

After performing the appropriate Inquiries, a claim that fails Inquiry 3 should be rejected under [35 U.S.C. 101 \(mpep-9015-appx-1.html#d0e302376\)](#), as not being drawn to patent-eligible subject matter. When making the rejection, identify the natural principle, identify that the claim is effectively directed to a natural principle itself, and explain the reason(s) that the additional claim features or combination of features, when the claim is taken as a whole, fail to integrate the natural principle into the claimed invention so that the natural principle is practically applied, and/or fail to be sufficient to ensure that the claim amounts to significantly more than the natural principle itself.

A sample rejection of the following claim could read as follows:

Claim 1. A method of determining effective dosage of insulin to a patient, comprising the steps of administering a dose of insulin to a patient, testing the patient's blood for the blood sugar level, and evaluating whether the insulin dosage is effective based on the blood sugar level.

Analysis:

The claim passes Inquiry 1 because it is drawn to a process.

The claim passes Inquiry 2 because a naturally occurring correlation between insulin and blood glucose levels is a limitation of the claim.

The claim does not pass Inquiry 3 because, although the additional steps integrate or make use of the correlation in the process by administering insulin in one step and testing for the correlation in another step, the steps are not sufficient to ensure that the claim amounts to significantly more than the correlation itself since every application of the correlation would require an administration of insulin and testing of blood to observe the relationship between insulin and blood glucose levels.

The rejection:

Claim 1 is rejected under [35 U.S.C. 101 \(mpep-9015-appx-1.html#d0e302376\)](#), because the claimed invention is directed to non-statutory subject matter because it is not a patent-eligible practical application of a law of nature. The claim is directed to a naturally occurring correlation between insulin and blood glucose levels. The combination of steps recited in the claim taken as a whole, including the steps of administering insulin to a patient and testing blood sugar levels, are not sufficient to qualify as a patent-eligible practical application as the claim covers every substantial practical application of the correlation.

D. Evaluating a Response

A proper response to a rejection based on failure to claim patent-eligible subject matter would be an amendment adding additional steps/features or amending existing steps/features that integrate the natural principle into the process (by practically applying or making use of the principle) and are sufficient to limit the application of the natural principle to more than the principle itself + steps that do more than simply "apply it" at a high level of generality. Examples of both eligible and ineligible hypothetical claims follow. It would also be proper for the applicant to present persuasive arguments that the additional steps add something significantly more to the claim than merely describing the natural principle. A showing that the steps are not routine, well-known or conventional could be persuasive.

For example, a claim that uses the natural disinfecting properties of sunlight would require additional steps beyond exposing an item requiring disinfection to sunlight. The additional steps could involve constructing a sanitizing device that uses ultraviolet light for disinfection with steps that integrate the ultraviolet light into the device and are sufficient to confine the use of the ultraviolet light to a particular application (not so broad as to cover all practical ways of applying ultraviolet light). A claim that sets forth the relationship between blood glucose levels and the incidence of diabetes would require additional steps that do significantly more to apply this principle than conventional blood sample testing or diagnostic activity based on recognizing a threshold blood glucose level. Such additional steps could involve a testing technique or treatment steps that would not be conventional or routine.

See the *2012 Interim Procedure for Laws of Nature* guidance memo issued July 3, 2012 and posted on the USPTO Web site (http://www.uspto.gov/patents/law/exam/2012_interim_guidance.pdf) ([mpep-0010-title-page.html#](#)) for additional examples.

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