distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C) *et seq*).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), of the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Does not have an annual effect on the economy of $100 million.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises to compete with foreign-based enterprises.

This determination is based upon the fact that the State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose an unfunded Mandate on State, local, or tribal governments or the private sector of $100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the federal regulation did not impose an unfunded mandate.

List of Subjects in 30 CFR Part 934

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 1, 2014.

Ervin Barchenger,

Acting Director, Western Region.

Editorial note: This document was received for publication by the Office of **Federal Register** on December 10, 2014.

For the reasons set out in the preamble, 30 CFR part 934 is amended as set forth below:

PART 934—NORTH DAKOTA

■ 1. The authority citation for part 934 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 934.15 is amended in the table by adding a new entry in chronological order by ''Date of Final Publication'' to read as follows:

§ 934.15 Approval of North Dakota regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
* * *	* * *	*
November 14, 2012	December 16, 2014	NDAC 69–05.2–05–02 NDAC 69–05.2–05–08 NDAC 69–05.2–06–01 NDAC 69–05.2–06–02 NDAC 69–05.2–10–01 NDAC 69–05.2–10–03 NDAC 69–05.2–10–07 NDAC 69–05.2–10–08 NDAC 69–05.2–10–09

■ 3. Section 934.16 is republished to read as follows:

§ 934.16 Required program amendments.

Pursuant to 30 CFR 732.17(f)(1), North Dakota is required to submit to OSM by the specified date the following written, proposed program amendment, or a description of an amendment to be proposed that meets the requirements of SMCRA and 30 CFR Chapter VII and a timetable for enactment that is consistent with North Dakota's established administrative or legislative

(a)–(cc) [Reserved]

[FR Doc. 2014–29384 Filed 12–15–14; 8:45 am]

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DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO–P–2014–0058]

2014 Interim Guidance on Patent Subject Matter Eligibility

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Examination guidance; request for comments.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) has prepared interim guidance (2014 Interim Guidance on Patent Subject Matter Eligibility, called ''Interim Eligibility Guidance'') for use by USPTO personnel in determining subject matter eligibility under 35 U.S.C. 101 in view of recent decisions by the U.S. Supreme Court (Supreme Court). This Interim Eligibility Guidance supplements the June 25, 2014, Preliminary Examination Instructions in view of the Supreme Court decision in *Alice Corp.* (June 2014 Preliminary Instructions) and supersedes the March 4, 2014, Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products (March 2014 Procedure) issued in view of the Supreme Court decisions in *Myriad* and *Mayo.* The USPTO is seeking public comment on this Interim Eligibility Guidance along with additional suggestions on claim examples for explanatory example sets.

DATES: *Effective Date:* This Interim Eligibility Guidance is effective on December 16, 2014. This Interim Eligibility Guidance applies to all applications filed before, on or after December 16, 2014.

Comment Deadline Date: To be ensured of consideration, written comments must be received on or before March 16, 2015.

ADDRESSES: Comments on this Interim Eligibility Guidance must be sent by electronic mail message over the Internet addressed to: *2014_interim_guidance@uspto.gov.* Electronic comments submitted in plain text are preferred, but also may be submitted in ADOBE® portable document format or MICROSOFT WORD® format. The comments will be available for viewing via the Office's Internet Web site (*http://www.uspto.gov*). Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT: Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, by telephone at 571–272–7728, or Michael Cygan, Senior Legal Advisor, Office of Patent Legal Administration, by telephone at 571–272–7700.

SUPPLEMENTARY INFORMATION: Section 2106 of the Manual of Patent Examining Procedure (MPEP) sets forth guidance for use by USPTO personnel in determining subject matter eligibility under 35 U.S.C. 101. *See* MPEP 2106 (9th ed. 2014). The USPTO has prepared this Interim Eligibility Guidance for use by USPTO personnel in determining subject matter eligibility under 35 U.S.C. 101 in view of recent decisions by the Supreme Court. The following Interim Eligibility Guidance on patent subject matter eligibility under 35 U.S.C. 101 supplements the June 25, 2014, Preliminary Examination Instructions in view of the Supreme Court Decision in *Alice Corporation Pty. Ltd.* v. *CLS Bank International, et al.*[1] (June 2014 Preliminary Instructions) and supersedes the March 4, 2014, Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products (March 2014 Procedure) [2] issued in view of the Supreme Court decisions in *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*[3] and *Mayo Collaborative Services* v. *Prometheus Laboratories Inc.*[4] Implementation of examination guidance on eligibility will be an iterative process continuing with periodic supplements based on developments in patent subject matter eligibility jurisprudence [5] and public feedback.

The USPTO is seeking written comments on this guidance, as well as additional suggestions for claim examples to use for examiner training. Further, the USPTO plans to hold a public forum in mid-January 2015 in order to discuss the guidance and next steps and to receive additional oral input. When the date and location are finalized, notice of the forum will be provided on the Office's Internet Web site (*http://www.uspto.gov*).

This Interim Eligibility Guidance does not constitute substantive rulemaking and does not have the force and effect of law. This Interim Eligibility Guidance sets out the Office's interpretation of the subject matter eligibility requirements of 35 U.S.C. 101 in view of recent decisions by the Supreme Court and the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), and advises the public and Office personnel on how these court decisions impact the provisions of MPEP 2105, 2106 and 2106.01. This Interim Eligibility Guidance has been developed as a matter of internal Office management and is not intended to create any right or benefit, substantive or procedural, enforceable by any party against the Office. Rejections will continue to be based upon the substantive law, and it is these rejections that are appealable. Failure of Office personnel to follow this Interim Eligibility Guidance is not, in itself, a proper basis for either an appeal or a petition.

This Interim Eligibility Guidance offers a comprehensive view of subject matter eligibility in line with *Alice Corp, Myriad, Mayo,* and the related body of case law, and is responsive to the public comments received pertaining to the March 2014 Procedure and the June 2014 Preliminary Instructions (*see* the Notice of Forum on the Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, and Natural Products, 79 FR 21736 (Apr. 17, 2014) and the Request for Comments and Extension of Comment Period on Examination Instruction and Guidance Pertaining to Patent-Eligible Subject Matter, 79 FR 36786 (June 30, 2014)). In conjunction with this Interim Eligibility Guidance, a set of explanatory examples relating to nature-based products is being released to replace the prior examples issued with the March 2014 Procedure and the related training. The explanatory examples relating to nature-based products address themes raised in the public comments and adopt many suggestions from the comments. Additional explanatory example sets relating to claims that do and do not amount to significantly more than a judicial exception are being developed and will be issued at a future date, taking into account suggestions already

[1] *Alice Corp. Pty. Ltd.* v. *CLS Bank Int'l,* 573 U.S. __, 134 S. Ct. 2347 (2014).

[2] This analysis differs from the March 2014 Procedure in certain respects. Note, for example, the test for determining whether a claim is directed to a ''product of nature'' exception is separated from the analysis of whether the claim includes significantly more than the exception. Also, the application of the overall analysis is based on claims *directed* to judicial exceptions (defined as claims reciting the exception, *i.e.,* set forth or described), rather than claims merely ''involving'' an exception. For instance, process claims that merely use a nature-based product are not necessarily subject to an analysis for markedly different characteristics. Additionally, the markedly different analysis focuses on characteristics that can include a product's structure, function, and/or other properties as compared to its naturally occurring counterpart in its natural state.

[3] *Association for Molecular Pathology* v. *Myriad Genetics, Inc.,* 569 U.S. __, 133 S. Ct. 2107 (2013).

[4] *Mayo Collaborative Serv.* v. *Prometheus Labs., Inc.,* 566 U.S. __, 132 S. Ct. 1289 (2012).

[5] The Court of Appeals for the Federal Circuit has a number of pending appeals that could result in further refinements to the eligibility guidance, including for example, *University of Utah Research Foundation* v. *Ambry Genetics Corp. (In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation*), No. 14–1361 (Fed. Cir. filed Mar. 18, 2014), and *Ariosa Diagnostics, Inc.* v. *Sequenom,*

future public comments, and any further judicial developments.

The June 2014 Preliminary Instructions superseded MPEP sections 2106(II)(A) and 2106(II)(B). MPEP 2105 is also superseded by this Interim Eligibility Guidance to the extent that it suggests that ''mere human intervention'' necessarily results in eligible subject matter. MPEP 2106.01 is additionally now superseded with this interim guidance. Examiners should continue to follow the MPEP for all other examination instructions. The following sections pertain to examining for patent subject matter eligibility with details on determining what applicant invented and making a rejection under 35 U.S.C. 101 and should be reviewed closely as they are not duplicated in this Interim Eligibility Guidance:

- MPEP 2103: Patent Examination Process
  - 2103(I): Determine What Applicant Has Invented and Is Seeking to Patent
  - 2103(II): Conduct a Thorough Search of the Prior Art
  - 2103(III): Determine Whether the Claimed Invention Complies With 35 U.S.C. 101
  - 2103(IV): Evaluate Application for Compliance With 35 U.S.C. 112
  - 2103(V): Determine Whether the Claimed Invention Complies With 35 U.S.C. 102 and 103
  - 2103(VI): Clearly Communicate Findings, Conclusions, and Their Bases
- MPEP 2104: Patentable Subject Matter
- MPEP 2105: Patentable Subject Matter—Living Subject Matter [6]
- MPEP 2106: Patent Subject Matter Eligibility
  - 2106(I): The Four Categories of Statutory Subject Matter
  - 2106(II): Judicial Exceptions to the Four Categories (*not* subsections (II)(A) and (II)(B))
  - 2106(III): Establish on the Record a *Prima Facie* Case

[6] To the extent that MPEP 2105 suggests that mere ''human intervention'' necessarily results in eligible subject matter, it is superseded by this Interim Eligibility Guidance. As explained herein, if human intervention has failed to confer markedly different characteristics on a product derived from nature, that product is a judicial exception (a product of nature exception). *See generally Myriad*; *In re Roslin Inst. (Edinburgh),* 750 F.3d. 1333 (Fed. Cir. 2014).

The current version of the MPEP (9th ed., March 2014) incorporates patent subject matter eligibility guidance issued as of November 2013.

This Interim Eligibility Guidance is divided into the following sections:

Flowchart: Eligibility Test for Products and Processes;

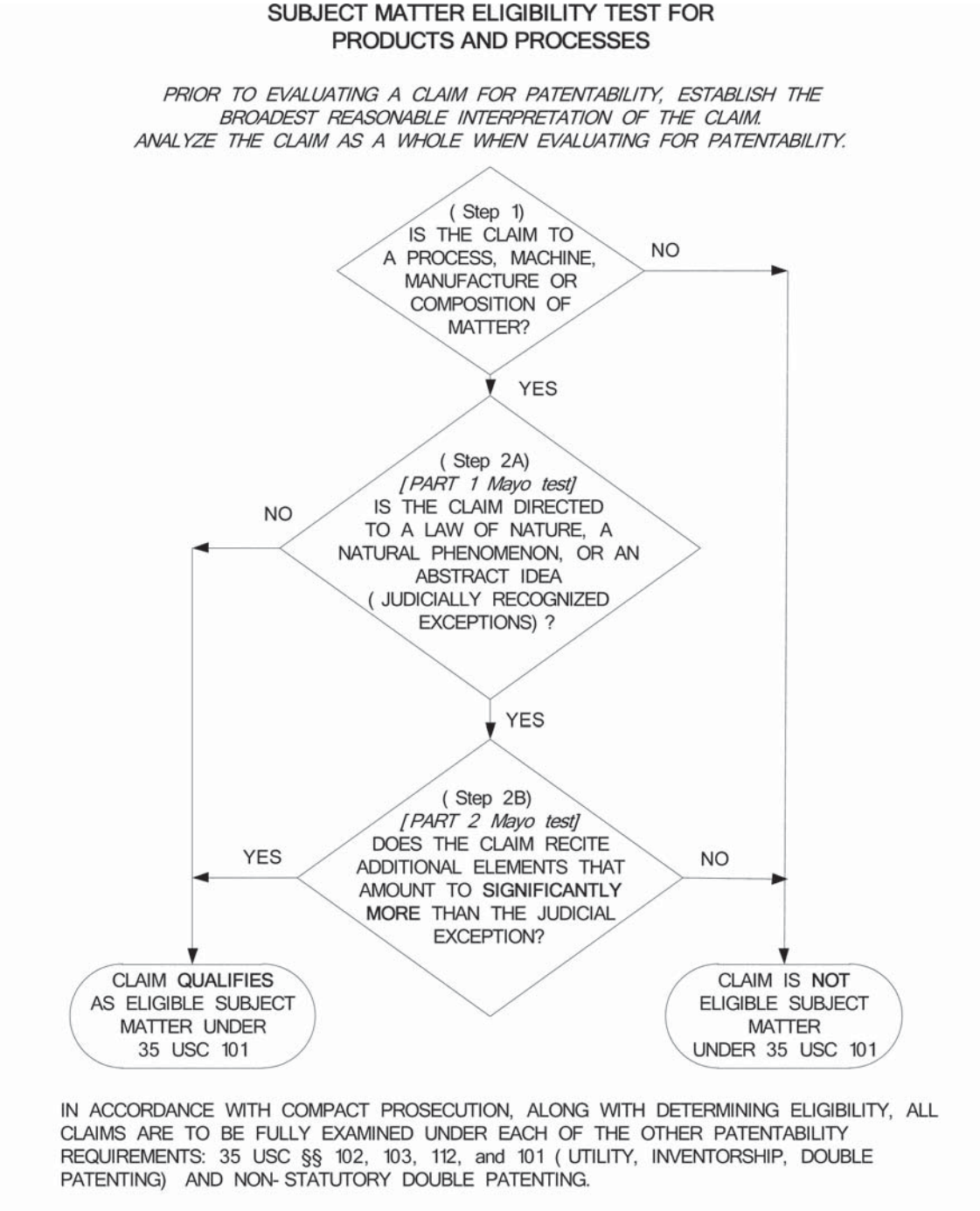
Part I: Two-part Analysis for Judicial Exceptions;

Part II: Complete Examination;

Part III: Sample Analysis; and

Part IV: Summaries of Court Decisions Relating to Laws of Nature, Natural Phenomena, and Abstract Ideas.

The following flowchart illustrates the subject matter eligibility analysis for products and processes to be used during examination for evaluating whether a claim is drawn to patent-eligible subject matter. It is recognized that under the controlling legal precedent there may be variations in the precise contours of the analysis for subject matter eligibility that will still achieve the same end result. The analysis set forth herein promotes examination efficiency and consistency across all technologies.



Notable changes from prior guidance:
- All claims (product and process) with a judicial exception (any type) are subject to the same steps.
- Claims including a nature- based product are analyzed in Step 2A to identify whether the claim is directed to (recites) a "product of nature" exception. This analysis compares the nature- based product in the claim to its naturally occurring counterpart to identify markedly different characteristics based on structure, function, and/ or properties. The analysis proceeds to Step 2B only when the claim is directed to an exception (when no markedly different characteristics are shown) .

2014 Interim Eligibility Guidance: In accordance with the existing two-step analysis for patent subject matter eligibility under 35 U.S.C. 101 explained in MPEP 2106, the claimed

one of the four statutory categories'' and (Step 2) ''must not be wholly directed to subject matter encompassing a judicially recognized exception.'' Referring to the attached flowchart titled Subject Matter

Processes, Step 1 is represented in diamond (1), which is explained in MPEP 2106(I). Step 2 is represented in diamonds (2A) and (2B) and is the subject of this Interim Eligibility

analysis from *Alice Corp.*[7] (also called the *Mayo* test) for claims directed to laws of nature, natural phenomena, and abstract ideas (the judicially recognized exceptions).

I. Two-Part Analysis for Judicial Exceptions

A. Flowchart Step 2A (Part 1 *Mayo* Test)—Determine whether the claim is *directed* to a law of nature, a natural phenomenon, or an abstract idea (judicial exceptions).

After determining what applicant has invented by reviewing the entire application disclosure and construing the claims in accordance with their broadest reasonable interpretation (MPEP 2103), determine whether the claim as a whole is directed to a judicial exception. A claim to a process, machine, manufacture or composition of matter (*Step 1: YES*) that is not directed to any judicial exceptions (*Step 2A: NO*) is eligible and needs no further eligibility analysis. A claim that is directed to at least one exception (*Step 2A: YES*) requires further analysis to determine whether the claim recites a patent-eligible application of the exception (*Step 2B*).

1. Determine What the Claim Is ''Directed to''

A claim is directed to a judicial exception when a law of nature, a natural phenomenon, or an abstract idea is recited (*i.e.,* set forth or described) in the claim. Such a claim requires closer scrutiny for eligibility because of the risk that it will ''tie up''[8] the excepted subject matter and pre-empt others from using the law of nature, natural phenomenon, or abstract idea. Courts tread carefully in scrutinizing such claims because at some level all inventions embody, use, reflect, rest upon, or apply a law of nature, natural phenomenon, or abstract idea.[9] To properly interpret the claim, it is important to understand what the applicant has invented and is seeking to patent.

For claims that may recite a judicial exception, but are directed to inventions that clearly do not seek to tie up the judicial exception, see Section I.B.3. regarding a streamlined eligibility analysis.

2. Identify the Judicial Exception Recited in the Claim

MPEP 2106(II) provides a detailed explanation of the judicial exceptions and their legal bases. It should be noted that there are no bright lines between the types of exceptions because many of these concepts can fall under several exceptions. For example, mathematical formulas are considered to be an exception as they express a scientific truth, but have been labelled by the courts as both abstract ideas and laws of nature. Likewise, ''products of nature'' are considered to be an exception because they tie up the use of naturally occurring things, but have been labelled as both laws of nature and natural phenomena. Thus, it is sufficient for this analysis to identify that the claimed concept aligns with at least one judicial exception.

Laws of nature and natural phenomena, as identified by the courts, include naturally occurring principles/substances and substances that do not have markedly different characteristics compared to what occurs in nature. See Section I.A.3. for a discussion of the markedly different characteristics analysis used to determine whether a claim that includes a nature-based product limitation recites an exception. The types of concepts courts have found to be laws of nature and natural phenomena are shown by these cases, which are intended to be illustrative and not limiting:

- An isolated DNA (*Myriad:* see Section III, Example 2);
- a correlation that is the consequence of how a certain compound is metabolized by the body (*Mayo:* see Section III, Example 5);
- electromagnetism to transmit signals (*Morse:*[10] see Section IV.A.1.); and
- the chemical principle underlying the union between fatty elements and water (*Tilghman:*[11] see Section IV.A.2.).

Abstract ideas have been identified by the courts by way of example, including fundamental economic practices, certain methods of organizing human activities, an idea 'of itself,' and mathematical relationships/formulas.[12] The types of concepts courts have found to be abstract ideas are shown by these cases, which are intended to be illustrative and not limiting:

- Mitigating settlement risk (*Alice:* see Section III, Example 6);
- hedging (*Bilski:*[13] see Section IV.A.5.);
- creating a contractual relationship (*buySAFE:*[14] see Section IV.C.3.);
- using advertising as an exchange or currency (*Ultramercial:*[15] see Section IV.C.4.);
- processing information through a clearinghouse (*Dealertrack:*[16] see Section IV.B.3.);
- comparing new and stored information and using rules to identify options (*SmartGene:*[17] see Section IV.B.4.);
- using categories to organize, store and transmit information (*Cyberfone:*[18] see Section IV.B.5.);
- organizing information through mathematical correlations (*Digitech:*[19] see Section IV.C.1.);
- managing a game of bingo (*Planet Bingo:*[20] see Section IV.C.2.);
- the Arrhenius equation for calculating the cure time of rubber (*Diehr:*[21] see Section III, Example 3);
- a formula for updating alarm limits (*Flook:*[22] see Section III, Example 4);
- a mathematical formula relating to standing wave phenomena (*Mackay Radio:*[23] see Section IV.A.3.); and
- a mathematical procedure for converting one form of numerical representation to another (*Benson:*[24] see Section IV.A.4.)

3. Nature-Based Products

a. Determine Whether the Markedly Different Characteristics Analysis Is Needed To Evaluate a Nature-Based Product Limitation Recited in a Claim

Nature-based products, as used herein, include both eligible and

[7] *Alice Corp.,* 134 S. Ct. at 2355.

[8] *Mayo,* 132 S. Ct. at 1301 (''[E]ven though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are 'the basic tools of scientific and technological work.' And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to 'apply the natural law,' or otherwise forecloses more future invention than the underlying discovery could reasonably justify'' (quoting *Gottschalk* v. *Benson,* 409 U.S. 63, 67 (1972)).

[9] An invention is not rendered ineligible for patent simply because it involves an abstract concept. Applications of such concepts ''to a new and useful end,'' remain eligible for patent protection. *Alice Corp.,* 134 S.Ct. at 2354 (quoting

[10] *O'Reilly* v. *Morse,* 56 U.S. 62 (1853).

[11] *Tilghman* v. *Proctor,* 102 U.S. 707 (1881).

[13] *Bilski* v. *Kappos,* 561 U.S. 593 (2010).

[14] *buySAFE, Inc.* v. *Google, Inc.,* ___ F.3d ___, 112 USPQ2d 1093 (Fed. Cir. 2014).

[15] *Ultramercial, LLC* v. *Hulu, LLC and WildTangent,* ___ F.3d ___, 112 USPQ2d 1750 (Fed. Cir. 2014).

[16] *Dealertrack Inc.* v. *Huber,* 674 F.3d 1315 (Fed. Cir. 2012).

[17] *SmartGene, Inc.* v. *Advanced Biological Labs., SA,* 555 Fed. Appx. 950 (Fed. Cir. 2014) (nonprecedential).

[18] *Cyberfone Sys.* v. *CNN Interactive Grp.,* 558 Fed. Appx. 988 (Fed. Cir. 2014) (nonprecedential).

[19] *Digitech Image Tech., LLC* v. *Electronics for Imaging, Inc.,* 758 F.3d 1344 (Fed. Cir. 2014).

[20] *Planet Bingo, LLC* v. *VKGS LLC,* ___ Fed. Appx. ___ (Fed. Cir. 2014) (nonprecedential).

[21] *Diamond* v. *Diehr,* 450 U.S. 175 (1981).

[22] *Parker* v. *Flook,* 437 U.S. 584 (1978).

[23] *Mackay Radio & Tel. Co.* v. *Radio Corp. of Am.,* 306 U.S. 86 (1939).

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