[3510-16-P]

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 [Insert date of publication in the FEDERAL REGISTER]. This Interim Eligibility Guidance applies to all applications filed before, on or after [Insert date of publication in the FEDERAL REGISTER].

COMMENT DEADLINE DATE: To be ensured of consideration, written comments must be received on or before [Insert date 90 days after the date of publication in the FEDERAL REGISTER].

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

[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).

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,

[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, Inc., No. 14-1139 (Fed. Cir. filed Dec. 4, 2013).

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 received from the public comments, 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]

[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

- 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

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

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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).

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;

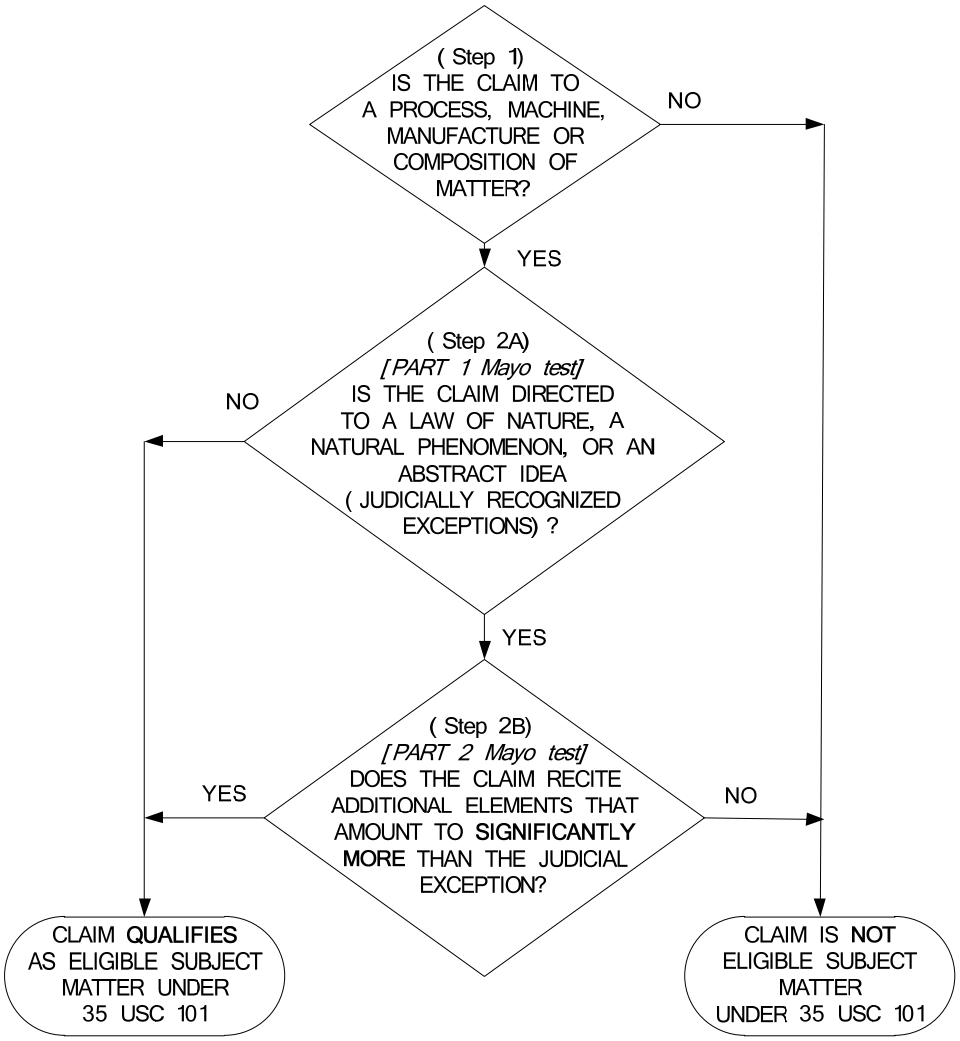
Part III: Sample Analysis; and

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.

SUBJECT MATTER ELIGIBILITY TEST FOR PRODUCTS AND PROCESSES

PRIOR TO EVALUATING A CLAIM FOR PATENTABILITY, ESTABLISH THE BROADEST REASONABLE INTERPRETATION OF THE CLAIM. ANALYZE THE CLAIM AS A WHOLE WHEN EVALUATING FOR PATENTABILITY.



IN ACCORDANCE WITH COMPACT PROSECUTION, ALONG WITH DETERMINING ELIGIBILITY, ALL CLAIMS ARE TO BE FULLY EXAMINED UNDER EACH OF THE OTHER PATENTABILITY REQUIREMENTS: 35 USC §§ 102, 103, 112, and 101 (UTILITY, INVENTORSHIP, DOUBLE PATENTING) AND NON-STATUTORY DOUBLE PATENTING.

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 invention (Step 1) "must be directed to 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 Eligibility Test for Products and 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 Guidance. Step 2 is the two-part 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

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

(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.

[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)).

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);

[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 Benson, 409 U.S. at 67).

- 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.);

[10] O'Reilly v. Morse, 56 U.S. 62 (1853).
[11] Tilghman v. Proctor, 102 U.S. 707 (1881).
[12] Alice Corp., 134 S. Ct. at 2355-56.
[13] Bilski v. Kappos, 561 U.S. 593 (2010).

- 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

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[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).

- 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 ineligible products and merely refer to the types of products subject to the markedly different characteristics analysis used to identify "product of nature" exceptions. Courts have held that naturally occurring products and some man-made products that are essentially no different from a naturally occurring product are "products of nature"[25] that fall under the laws of nature or natural phenomena exception. To determine whether a claim that includes a nature-based product limitation recites a "product of nature" exception, use the markedly different characteristics analysis to evaluate the nature-based product limitation (discussed in section I.A.3.b). A claim that recites a nature-based product limitation that does not exhibit markedly different characteristics from its naturally occurring counterpart in its natural state is directed to a "product of nature" exception (Step 2A: YES).

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[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).
[24] Benson, 409 U.S. at 63.
[25] Myriad, 133 S. Ct. at 2111.

Care should be taken not to overly extend the markedly different characteristics analysis to products that when viewed as a whole are not nature-based. For claims that recite a nature-based product limitation (which may or may not be a "product of nature" exception) but are directed to inventions that clearly do not seek to tie up any judicial exception, see Section I.B.3. regarding a streamlined eligibility analysis. In such cases, it would not be necessary to conduct a markedly different characteristics analysis.

A nature-based product can be claimed by itself (e.g., "a Lactobacillus bacterium") or as one or more limitations of a claim (e.g., "a probiotic composition comprising a mixture of Lactobacillus and milk in a container"). The markedly different characteristics analysis should be applied only to the nature-based product limitations in the claim to determine whether the nature-based products are "product of nature" exceptions. When the nature-based product is produced by combining multiple components, the markedly different characteristics analysis should be applied to the resultant nature-based combination, rather than its component parts. In the example above, the mixture of Lactobacillus and milk should be analyzed for markedly different characteristics, rather than the Lactobacillus separately and the milk separately. The container would not be subject to the markedly different characteristics analysis as it is not a nature-based product, but would be evaluated in Step 2B if it is determined that the mixture of Lactobacillus and milk does not have markedly different characteristics from any naturally occurring counterpart and thus is a "product of nature" exception.

For a product-by-process claim, the analysis turns on whether the nature-based product in the claim has markedly different characteristics from its naturally occurring counterpart. (See MPEP 2113 for product-by-process claims.)

A process claim is not subject to the markedly different analysis for nature-based products used in the process, except in the limited situation where a process claim is drafted in such a way[26] that there is no difference in substance from a product claim (e.g., "a method of providing an apple.").

b. Markedly Different Characteristics Analysis: Structure, Function and/or Other Properties[27]

The markedly different characteristics analysis compares the nature-based product limitation to its naturally occurring counterpart in its natural state. When there is no naturally occurring counterpart to the nature-based product, the comparison should be made to the closest naturally occurring counterpart. In the case of a nature-based combination, the closest counterpart may be the individual nature-based components that form the combination, i.e., the characteristics of the claimed nature-based combination are compared to the characteristics of the components in their natural state.

[26] Alice Corp., 134 S. Ct. at 2360.

Markedly different characteristics can be expressed as the product's structure, function, and/or other properties,[28] and will be evaluated based on what is recited in the claim on a case-by-case basis. As seen by the examples that are being released in conjunction with this Interim Eligibility Guidance, even a small change can result in markedly different characteristics from the product's naturally occurring counterpart. In accordance with this analysis, a product that is purified or isolated, for example, will be eligible when there is a resultant change in characteristics sufficient to show a marked difference from the product's naturally occurring counterpart. If the claim recites a nature-based product limitation that does not exhibit markedly different characteristics, the claim is directed to a "product of nature" exception (a law of nature or naturally occurring phenomenon), and the claim will require further analysis to determine eligibility based on whether additional elements add significantly more to the exception.

Non-limiting examples of the types of characteristics considered by the courts when determining whether there is a marked difference include:

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[27] This revised analysis represents a change from prior guidance, because now changes in functional characteristics and other non-structural properties can evidence markedly different characteristics, whereas in the March 2014 Procedure only structural changes were sufficient to show a marked difference.

[28] To show a marked difference, a characteristic must be changed as compared to nature, and cannot be an inherent or innate characteristic of the naturally occurring counterpart. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) ("[The inventor did] not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable."); In re Marden, 47 F.2d 958 (CCPA 1931) (eligibility of a claim to ductile vanadium held ineligible, because the "ductility or malleability of vanadium is . . . one of its inherent characteristics and not a characteristic given to it by virtue of a new combination with other materials or which characteristic is brought about by some chemical reaction or agency which changes its inherent characteristics"). Further, a difference in a characteristic that came about or was produced independently of any effort or influence by applicant cannot show a marked difference. Roslin, 750 F.3d at 1338 (Because "any phenotypic differences came about or were produced 'quite independently of any effort of the patentee'" and were "uninfluenced by Roslin's efforts", they "do not confer eligibility on their claimed subject matter" (quoting Funk Bros.)).

- Biological or pharmacological functions or activities;[29]
- Chemical and physical properties;[30]
- Phenotype, including functional and structural characteristics;[31] and
- Structure and form, whether chemical, genetic or physical.[32]

If the claim includes a nature-based product that has markedly different characteristics, the claim does not recite a "product of nature" exception and is eligible (Step 2A: NO) unless the claim recites another exception (such as a law of nature or abstract idea, or a different natural phenomenon). If the claim includes a product having no markedly different characteristics from the product's naturally occurring counterpart in its natural state, the claim is directed to an exception (Step 2A: YES), and the eligibility analysis must proceed to Step 2B to determine if any additional elements in the claim add significantly more to the exception. For claims that are to a single nature-based product, once a markedly different characteristic in that product is shown, no further analysis would be necessary for eligibility because no "product of nature" exception is recited (i.e., Step 2B is not necessary because the answer to Step 2A is NO). This is a change

[29] See, e.g., Funk Bros., 333 U.S. at 130-31 (properties and functions of bacteria such as a state of inhibition or non-inhibition and the ability to infect leguminous plants); Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (genetically modified bacterium's ability to degrade hydrocarbons); In re King, 107 F.2d 618 (CCPA 1939) (the ability of vitamin C to prevent and treat scurvy); Myriad, 133 S. Ct. at 2111, 2116-17 (the protein-encoding information of a nucleic acid).

[30] See, e.g., Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103-04 (S.D.N.Y. 1911) (the alkalinity of a chemical compound); Marden, 47 F.2d at 958 (the ductility or malleability of metals); Funk Bros., 333 U.S. at 130 ("The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the store-house of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.").

[31] See, e.g., Roslin, 750 F.3d at 1338 (phenotype, including functional and structural characteristics, e.g., the shape, size, color, and behavior of an organism).

[32] See, e.g., Chakrabarty, 447 U.S. at 305 and n.1 (the physical presence of plasmids in a bacterial cell); Parke-Davis, 189 F. at 100, 103 (claimed chemical was a "nonsalt" and a "crystalline substance"); Myriad, 133 S. Ct. at 2116, 2119 (nucleotide sequence of DNA); Roslin, 750 F.3d at 1338-39 (the genetic makeup (genotype) of a cell or organism).

from prior guidance because the inquiry as to whether the claim amounts to significantly more than a "product of nature" exception is not relevant to claims that do not recite an exception. Thus, a claim can be found eligible based solely on a showing that the nature-based product in the claim has markedly different characteristics and thus is not a "product of nature" exception, when no other exception is recited in the claim.

If a rejection under 35 U.S.C. 101 is ultimately made, the rejection should identify the exception as it is recited (i.e., set forth or described) in the claim, and explain why it is an exception providing reasons why the product does not have markedly different characteristics from its naturally occurring counterpart in its natural state.

B. Flowchart Step 2B (Part 2 Mayo test) - Determine whether any element, or combination of elements, in the claim is sufficient to ensure that the claim amounts to significantly more than the judicial exception.

A claim directed to a judicial exception must be analyzed to determine whether the elements of the claim, considered both individually and as an ordered combination, are sufficient to ensure that the claim as a whole amounts to significantly more than the exception itself – this has been termed a search for an "inventive concept."[33] To be patent-eligible, a claim that is directed to a judicial exception must include additional

features to ensure that the claim describes a process or product that applies the exception in a meaningful way, such that it is more than a drafting effort designed to monopolize the exception. It is important to consider the claim as whole. Individual elements viewed on their own may not appear to add significantly more to the claim, but when combined may amount to significantly more than the exception. Every claim must be examined individually, based on the particular elements recited therein, and should not be judged to automatically stand or fall with similar claims in an application.

1. "Significantly More"

The Supreme Court has identified a number of considerations for determining whether a claim with additional elements amounts to significantly more than the judicial exception itself. The following are examples of these considerations, which are not intended to be exclusive or limiting. Limitations that may be enough to qualify as "significantly more" when recited in a claim with a judicial exception include:

- Improvements to another technology or technical field;[34]
- Improvements to the functioning of the computer itself;[35]
- Applying the judicial exception with, or by use of, a particular machine;[36]

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[33] Alice Corp., 134 S. Ct. at 2357.

[34] Alice Corp., 134 S. Ct. at 2359 (citing Diehr, 450 U.S. at 177-78) (a mathematical formula applied in a specific rubber molding process).

[35] Id., at 2359.

[36] Bilski, 130 S. Ct. at 3227 ("The 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.").

- Effecting a transformation or reduction of a particular article to a different state or thing;[37]
- Adding a specific limitation other than what is well-understood, routine and conventional in the field, or adding unconventional steps that confine the claim to a particular useful application;[38] or
- Other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment.[39]

Limitations that were found not to be enough to qualify as "significantly more" when recited in a claim with a judicial exception include:

- Adding the words "apply it" (or an equivalent) with the judicial exception, or mere instructions to implement an abstract idea on a computer;[40]
- Simply appending well-understood, routine and conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception, e.g., a claim to an abstract idea requiring no more than a generic

[37] Diehr, 450 U.S. at 184 ("That respondents' claims [to a specific rubber molding process] involve the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing cannot be disputed."). See also Benson, 409 U.S. at 70 ("Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines. So it is that a patent in the process of 'manufacturing fat acids and glycerine from fatty bodies by the action of water at a high temperature and pressure' was sustained in Tilghman, 102 U.S. at 721").

[38] Mayo, 132 S. Ct. at 1299, 1302 (claim ineligible because the recited "instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field," which was "[u]nlike, say, a typical patent on a new drug or a new way of using an existing drug").

[39] Alice Corp., 134 S. Ct. at 2360 (noting that none of the hardware recited "offers a meaningful limitation beyond generally linking 'the use of the [method] to a particular technological environment,' that is, implementation via computers" (citing Bilski, 561 U.S. at 610, 611)).

computer to perform generic computer functions that are well-understood, routine and conventional activities previously known to the industry;[41]

- Adding insignificant extrasolution activity to the judicial exception, e.g., mere data gathering in conjunction with a law of nature or abstract idea;[42] or
- Generally linking the use of the judicial exception to a particular technological environment or field of use.[43]

Section III provides examples of claims analyzed under this framework.

If the claim as a whole does recite significantly more than the exception itself, the claim is eligible (Step 2B: YES), and the eligibility analysis is complete. If there are no meaningful limitations in the claim that transform the exception into a patent-eligible application, such that the claim does not amount to significantly more than the exception itself, the claim is not patent-eligible (Step 2B: NO) and should be rejected under 35 U.S.C. 101. In the rejection, identify the exception by referring to where it is recited (i.e., set forth or described) in the claim and explain why it is considered an exception. Then, if the claim includes additional elements, identify the elements in the rejection and

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[40] Id. at 2358 (simply implementing a mathematical principle on a physical machine, namely a computer (citing Mayo, 132 S. Ct. at 1301)).

[41] Id. at 2359 (using a computer to obtain data, adjust account balances, and issue automated instructions); Mayo, 132 S. Ct. at 1300 (telling a doctor to measure metabolite levels in the blood using any known process).

[42] Mayo, 132 S. Ct. at 1297-98 (measuring metabolites of a drug administered to a patient); Flook, 437 U.S. at 589-90 (1978) (adjusting an alarm limit variable to a figure computed according to a mathematical formula).

[43] Mayo, 132 S. Ct. at 1300-01 (citing Bilski, 130 S. Ct. 3223-24) (limiting hedging to use in commodities and energy markets); Flook, 437 U.S. at 589-90.

explain why they do not add significantly more to the exception. Also see MPEP 2103(VI) and 2106(III) for instructions on making the rejection.

2. A Claim Reciting a Plurality of Exceptions

For a claim that is directed to a plurality of exceptions, conduct the eligibility analysis for one of the exceptions. If the claim recites an element or combination of elements that amount to significantly more than that exception, consider whether those additional elements also amount to significantly more for the other claimed exception(s), which ensures that the claim does not have a pre-emptive effect with respect to any of the recited exceptions. Additional elements that satisfy Step 2B for one exception will likely satisfy Step 2B for all exceptions in a claim. On the other hand, if the claim fails under Step 2B for one exception, the claim is ineligible, and no further eligibility analysis is needed.

3. Streamlined Eligibility Analysis

For purposes of efficiency in examination, a streamlined eligibility analysis can be used for a claim that may or may not recite a judicial exception but, when viewed as a whole, clearly does not seek to tie up any judicial exception such that others cannot practice it. Such claims do not need to proceed through the full analysis herein as their eligibility will be self-evident. However, if there is doubt as to whether the applicant is effectively

seeking coverage for a judicial exception itself, the full analysis should be conducted to determine whether the claim recites significantly more than the judicial exception.

For instance, a claim directed to a complex manufactured industrial product or process that recites meaningful limitations along with a judicial exception may sufficiently limit its practical application so that a full eligibility analysis is not needed. As an example, a robotic arm assembly having a control system that operates using certain mathematical relationships is clearly not an attempt to tie up use of the mathematical relationships and would not require a full analysis to determine eligibility. Also, a claim that recites a nature-based product, but clearly does not attempt to tie up the nature-based product, does not require a markedly different characteristics analysis to identify a "product of nature" exception. As an example, a claim directed to an artificial hip prosthesis coated with a naturally occurring mineral is not an attempt to tie up the mineral. Similarly, claimed products that merely include ancillary nature-based components, such as a claim that is directed to a cellphone with an electrical contact made of gold or a plastic chair with wood trim, would not require analysis of the nature-based component to identify a "product of nature" exception because such claims do not attempt to improperly tie up the nature-based product.

II. Complete Examination

Regardless of whether a rejection under 35 U.S.C. 101 is made, a complete examination should be made for every claim under each of the other patentability requirements:

35 U.S.C. 102, 103, 112, and 101 (utility, inventorship and double patenting) and non-statutory double patenting. See MPEP 2103 et seq. and 2106(III).

III. Sample Analyses

The following examples, based upon Supreme Court decisions, use the Interim Eligibility Guidance and flowchart to analyze claims for subject matter eligibility.

Example 1. Diamond v. Chakrabarty[44] (U.S. Patent No. 4,259,444)

Background: Stable energy-generating plasmids that provide hydrocarbon degradative pathways exist within certain bacteria in nature. Different plasmids provide the ability to degrade different hydrocarbons, e.g., one plasmid provides the ability to degrade camphor, and a different plasmid provides the ability to degrade octane. Pseudomonas bacteria are naturally occurring bacteria. Naturally occurring Pseudomonas bacteria containing one stable energy-generating plasmid and capable of degrading a single type of hydrocarbon are known.

Representative Claim:

> A bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

[44] Chakrabarty, 447 U.S. at 303.

Analysis: The claim is directed to a statutory category, e.g., a manufacture or composition of matter (Step 1: YES) and recites a nature-based product (a bacterium). To determine whether the claim is directed to a "product of nature" exception, the nature-based product is analyzed using the markedly different characteristics analysis.

The claimed bacterium has a different functional characteristic from naturally occurring Pseudomonas bacteria, i.e., it is able to degrade at least two different hydrocarbons as compared to naturally occurring Pseudomonas bacteria that can only degrade a single hydrocarbon. The claimed bacterium also has a different structural characteristic, i.e., it was genetically modified to include more plasmids than are found in a single naturally occurring Pseudomonas bacterium. The bacterium is new with markedly different characteristics from any found in nature, due to the additional plasmids and resultant capacity for degrading multiple hydrocarbon components of oil. These different functional and structural characteristics rise to the level of a marked difference, and accordingly the claimed bacterium is not a "product of nature" exception. Thus, the claim is not directed to an exception (Step 2A: NO). The claim is eligible.

Example 2. Association for Molecular Pathology v. Myriad Genetics, Inc. (U.S. Patent No. 5,747,282)

Background: A human gene is a naturally occurring segment of DNA that codes for a protein. In nature, human genes are linked together by covalent bonds to form long chains of DNA called chromosomes. The inventors discovered the location and nucleotide sequence of a naturally occurring human gene called BRCA1. The BRCA1

gene encodes a polypeptide called BRCA1, which helps repair damaged DNA and prevent tumor formation. There are many naturally-occurring mutations in the BRCA1 gene. Some mutations are harmless, but others can dramatically increase a person's risk of developing breast and ovarian cancer.

Knowledge of the location and nucleotide sequence of the BRCA1 gene allows it to be isolated so that it can be studied, manipulated, or used. Isolated genes can be made in two different ways. The first way is to physically remove the gene from its natural location on the human chromosome by breaking two covalent bonds – one on each end of the gene – that connect the gene with the rest of the chromosome in nature. The second way is to synthesize the gene in a laboratory, e.g., by linking together nucleotides to form the naturally occurring sequence of the gene. Both ways result in a gene that is "isolated" from its natural environment, i.e., removed from the chromosome in which it occurs in nature.

The BRCA1 gene is about 80,000 nucleotides long, including several introns and several exons. In nature, the BRCA1 polypeptide is produced from the BRCA1 gene through an intermediate product called an mRNA. The natural creation of the BRCA1 mRNA in human cells involves splicing (removal) of the introns, and results in an exons-only molecule. The inventors used the mRNA to create an exons-only molecule called a complementary DNA (cDNA), which contains the same protein-encoding information as the BRCA1 gene, but omits the non-coding portions (introns) of the gene. The nucleotide

sequence of this cDNA was disclosed as SEQ ID NO:1, and the amino acid sequence of the BRCA1 polypeptide as SEQ ID NO:2.

Representative Claims:

> Claim 1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
>
> Claim 2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.

Analysis: The claims are directed to a statutory category, e.g., a composition of matter (Step 1: YES), and recite nature-based products (a DNA). Thus, the markedly different analysis is used to determine if that nature-based product is a "product of nature" exception.

Claim 1: The claim encompasses isolated DNA that has the same nucleotide sequence as the naturally occurring BRCA1 gene. The isolation of the claimed DNA results in a different structural characteristic than the natural gene, because the natural gene has covalent bonds on the ends that connect the gene to the chromosome which the claimed DNA lacks. However, the claimed DNA is otherwise structurally identical to the natural gene, e.g., it has the same genetic structure and nucleotide sequence as the BRCA1 gene in nature. The claimed DNA has no different functional characteristics, i.e., it encodes the same protein as the natural gene. Under the holding of Myriad, this isolated but otherwise unchanged DNA is not eligible because it is not different enough from what exists in nature to avoid improperly tying up the future use and study of the naturally occurring BRCA1 gene. In other words, the claimed DNA is different, but not markedly

different, from its naturally occurring counterpart (BRCA 1 gene), and thus is directed to a "product of nature" exception (Step 2A: YES).

A claim directed to an exception should be analyzed to determine whether any element, or combination of elements, in the claim is sufficient to ensure that the claim amounts to significantly more than the exception. Claim 1 does not include any additional features that could add significantly more to the exception (Step 2B: NO). The claim is not eligible and should be rejected under 35 U.S.C. 101.

Claim 2: The claim is limited to a DNA having the nucleotide sequence of SEQ ID NO: 1. As disclosed in the specification, SEQ ID NO: 1 is an exons-only sequence of a cDNA created by the inventors. The claimed DNA therefore has different structural characteristics than the naturally occurring BRCA1 gene, e.g., in addition to lacking covalent bonds on its ends, it has a different nucleotide sequence (SEQ ID NO: 1 includes only exons, as compared to the natural sequence containing both exons and introns). The claimed DNA has no different functional characteristics, i.e., it encodes the same protein as the natural gene. Here, the differences in structural characteristics between the claimed DNA and the natural gene are significant, e.g., they are enough to ensure that the claim is not improperly tying up the future use of the BRCA1 gene. Thus, they rise to the level of a marked difference, and the claimed DNA is not a "product of nature" exception. Thus, the claim is not directed to an exception (Step 2A: NO). The claim is eligible.

Example 3. Diamond v. Diehr (U.S. Patent No. 4,344,142)

Background: The claimed invention is a process for molding raw, uncured synthetic rubber into cured precision products. The process uses a mold for precisely shaping the uncured material under heat and pressure and then curing the synthetic rubber in the mold so that the product will retain its shape and be functionally operative after the molding is completed. Achieving the perfect cure depends upon several factors including the thickness of the article to be molded, the temperature of the molding process, and the amount of time that the article is allowed to remain in the press. It is possible to calculate when to open the press and remove the cured product using well-known time, temperature, and cure relationships by means of the Arrhenius equation. The inventors characterize their invention as the process of constantly measuring the actual temperature inside the mold, and automatically feeding these temperature measurements into a computer that repeatedly recalculates the cure time by use of the Arrhenius equation. When the recalculated time equals the actual time that has elapsed since the press was closed, the computer signals a device to open the press.

Representative Claim:

> Claim 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.

Analysis: The claim is directed to a statutory category, i.e., a process (Step 1: YES). The claim recites the Arrhenius equation, which is the mathematical formula: ln v = CZ+x. The court noted that an algorithm, or mathematical formula, is like a law of nature, which cannot be the subject of a patent. The claimed process when viewed as a whole focuses on the use of the Arrhenius equation to cure synthetic rubber. Thus, the claim is directed to an exception (Step 2A: YES).

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. The specifically disclosed and claimed constant measurement of temperature at a mold cavity of a rubber-molding press and the claimed repetitive computer recalculation of the appropriate cure time using the constantly updated measurements are additional elements that provide "something more" than mere computer implementation of calculation of the Arrhenius equation. Further, the claimed steps act in concert to transform raw, uncured rubber to cured molded rubber. The combination of steps recited in addition to the mathematical formula show that the claim is not to the formula in isolation, but rather that the steps impose meaningful limits that apply the formula to

improve an existing technological process. Thus, the claim amounts to significantly more than the judicial exception (Step 2B: YES). The claim is eligible.

Note: The Supreme Court has also characterized mathematical formulas as abstract ideas. As noted, all claims that are directed to a judicial exception, regardless of what the exception is called, are subject to the same analysis.

Example 4. Parker v. Flook

Background: The invention is a method of updating alarm limits using a mathematical formula. An "alarm limit" is a number. During catalytic conversion processes, operating conditions such as temperature, pressure, and flow rates are constantly monitored. When any of these "process variables" exceeds a predetermined alarm limit, an alarm may signal the presence of an abnormal condition indicating either inefficiency or perhaps danger. The formula for updating alarm limits is used in a catalytic conversion processing system; however, there is no disclosure relating to that system, such as the chemical processes at work, the monitoring of process conditions, the determination of variables in the formula from process conditions, or the means of setting off an alarm or adjusting an alarm system.

> Representative Claim:
>
> Claim 1. A method for updating the value of at least one alarm limit on at least one process variable involved in a process comprising the catalytic chemical conversion of hydrocarbons wherein said alarm limit has a current value of B_o+K wherein B_o is the current alarm base and K is a predetermined alarm offset which comprises:

(1) Determining the present value of said process variable, said present value being defined as PVL;
(2) Determining a new alarm base B_1, using the following equation: $B_1=B_o(1.0-F) + PVL(F)$ where F is a predetermined number greater than zero and less than 1.0;
(3) Determining an updated alarm limit which is defined as B_1+GK; and thereafter
(4) Adjusting said alarm limit to said updated alarm limit value.

Analysis: The claim is directed to a statutory category, i.e., a process (Step 1: YES). The claim recites the mathematical formula "$B_1=B_o(1.0-F) + PVL(F)$". The claimed invention focuses on the calculation of the number representing the alarm limit value using the mathematical formula. Thus, the claim is directed to a mathematical formula, which is like a law of nature that falls within the exceptions to patent-eligible subject matter (Step 2A: YES).

A process is not unpatentable simply because it contains a law of nature or mathematical algorithm. The claim as a whole must be analyzed to determine what additional elements are recited in the claim. The claimed formula is limited by the steps of gathering the input variables and carrying out the calculation to update the number describing the alarm limit, and by the field of technology for which it is to be used. The determination of chemical process variables, and the use of a generic computer to calculate values, is routine and conventional in the field of chemical processing. Adjusting the alarm limit based on the solution to the mathematical formula is merely post-solution activity that could be attached to almost any formula. Limiting the claim to petrochemical and oil-refining industries, such that the claim does not seek to wholly preempt the mathematical formula, is a field-of-use limitation that does not impose meaningful limits on the

mathematical formula. Moreover, when considered as an ordered combination, the claim is nothing more than a purely conventional computerized implementation of applicant's formula. Therefore, the claim as a whole does not provide significantly more than a generic computer upon which the claimed formula is calculated. Thus, the claim does not amount to significantly more than the judicial exception itself (Step 2B: NO). The claim is not eligible and should be rejected under 35 U.S.C. 101.

Example 5. Mayo v. Prometheus (U.S. Patent No. 6,355,623)

Background: The invention is a method of assisting doctors who use thiopurine drugs to treat patients with autoimmune diseases. The method helps doctors determine whether a given dosage level is too low or too high, based on the relationship between the concentration in the blood of a thiopurine metabolite (6-thioguanine) and the likelihood that the drug dosage will be ineffective or induce harmful side-effects. The relationship is a natural consequence of the ways in which thiopurine compounds are metabolized by the body, even though human action is needed to trigger a manifestation of the relationship.

Representative Claim

> Claim 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 $8x10^8$ 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 $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Analysis: The claim is directed to a statutory category, i.e., a process (Step 1: YES). The claim sets forth 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. While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The claim recites that relation and, thus, is directed towards a natural law (Step 2A: YES).

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. The "administering" step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs. That audience is a pre-existing audience; doctors used thiopurine drugs to treat patients suffering from autoimmune disorders long before anyone asserted these claims. The "wherein" clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that the doctor should take those laws into account when treating the patient. The "determining" step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use. 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. Even though the laws of nature at issue are narrow laws that may have limited applications, the claim does not amount to significantly more than the natural law itself (Step 2B: NO). The claim is not eligible and should be rejected under 35 U.S.C. 101.

Example 6. Alice Corp. v. CLS Bank (U.S. Patent Nos. 5,970,479 and 7,725,375) Background: The claims at issue relate to a computerized scheme for mitigating "settlement risk"; i.e., the risk that only one party to an agreed-upon financial exchange will satisfy its obligation. In particular, the claims are designed to facilitate the exchange of financial obligations between two parties by using a computer system as a third-party intermediary. The intermediary creates "shadow" credit and debit records (i.e., account ledgers) that mirror the balances in the parties' real-world accounts at "exchange institutions" (e.g., banks). The intermediary updates the shadow records in real time as transactions are entered, allowing only those transactions for which the parties' updated shadow records indicate sufficient resources to satisfy their mutual obligations. At the end of the day, the intermediary instructs the relevant financial institutions to carry out the "permitted" transactions in accordance with the updated shadow records, thus mitigating the risk that only one party will perform the agreed-upon exchange. The invention is claimed in the form of a computer-implemented process, a system enabling that process, and a computer-readable medium enabling that process to be performed by a computer.

Representative Method Claim (U.S. Patent No. 5,970,479):

> Claim 33. A method of exchanging obligations as between parties, each party holding a credit record and a debit record with an exchange institution, the credit records and debit records for exchange of predetermined obligations, the method comprising the steps of:
> (a) creating a shadow credit record and a shadow debit record for each stakeholder party to be held independently by a supervisory institution from the exchange institutions;
> (b) obtaining from each exchange institution a start-of-day balance for each shadow credit record and shadow debit record;
> (c) for every transaction resulting in an exchange obligation, the supervisory institution adjusting each respective party's shadow credit record or shadow debit record, allowing only these transactions that do not result in the value of the shadow debit record being less than the value of the shadow credit record at any time, each said adjustment taking place in chronological order, and
> (d) at the end-of-day, the supervisory institution instructing one of the exchange institutions to exchange credits or debits to the credit record and debit record of the respective parties in accordance with the adjustments of the said permitted transactions, the credits and debits being irrevocable, time invariant obligations placed on the exchange institutions.[45]

Analysis: The claim is directed to a statutory category, i.e., a process (Step 1: YES). The claim recites the concept of managing settlement risk through an intermediary, i.e., intermediated settlement. The claimed invention describes the procedures an intermediary should take in managing settlement risk between two parties, i.e., specific details of intermediating settlement. Intermediated settlement, like risk hedging in Bilski, is not a preexisting fundamental truth but rather is a longstanding commercial practice (a method of organizing human activity). The concept of intermediated settlement is a fundamental economic practice long prevalent in our system of commerce, which is in

[45] In Alice Corp., the parties stipulated that the method was performed by a computer, despite the lack of a computer recitation in the representative method claim.

the realm of abstract ideas identified by the Supreme Court. Thus, the claim is directed to the abstract idea of intermediated settlement (Step 2A: YES).

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. Although a computer acts as the intermediary in the claimed method, the claims do no more than implement the abstract idea of intermediated settlement on a generic computer. Using a computer to create and maintain "shadow" accounts amounts to electronic recordkeeping, which is one of the most basic functions of a computer. The same is true with respect to the use of a computer to obtain data, adjust account balances, and issue automated instructions. All of these computer functions are "well-understood, routine, conventional activit[ies]" previously known to the industry. Each step does no more than require a generic computer to perform generic computer functions. Considered as an ordered combination, the computer components of the method add nothing that is not already present when the steps are considered separately, and thus simply recite the concept of intermediated settlement as performed by a generic computer. The claims do not purport to improve the functioning of the computer itself, or to improve any other technology or technical field. Use of an unspecified, generic computer does not transform an abstract idea into a patent-eligible invention. Thus, the claim does not amount to significantly more than the abstract idea itself (Step 2B: NO). The claim is not eligible and should be rejected under 35 U.S.C. 101.

Representative System Claim (U.S. Patent No. 7,725,375)

> Claim 26. A data processing system to enable the exchange of an obligation between parties, the system comprising:
> a communications controller,
> a first party device, coupled to said communications controller,
> a data storage unit having stored therein
> (a) information about a first account for a first party, independent from a second account maintained by a first exchange institution, and
>
> (b) information about a third account for a second party, independent from a fourth account maintained by a second exchange institution; and
>
> a computer, coupled to said data storage unit and said communications controller, that is configured to
> (a) receive a transaction from said first party device via said communications controller;
>
> (b) electronically adjust said first account and said third account in order to effect an exchange obligation arising from said transaction between said first party and said second party after ensuring that said first party and/or said second party have adequate value in said first account and/or said third account, respectively; and
>
> (c) generate an instruction to said first exchange institution and/or said second exchange institution to adjust said second account and/or said fourth account in accordance with the adjustment of said first account and/or third account, wherein said instruction being an irrevocable, time invariant obligation placed on said first exchange institution and/or said second exchange institution.

Analysis: The claim is directed to a statutory category, i.e., a machine (Step 1: YES). As discussed for the method claim, the claim recites the concept of intermediated settlement and is directed to an abstract idea (Step 2A: YES).

Looking again to see what additional features are recited in the claim, the system includes a communications controller, a first party device, a data storage device, and a computer. The claimed hardware is generic hardware that nearly every computer will include. None

of the hardware offers a meaningful limitation beyond generally linking the system to a particular technological environment, that is, implementation via computers. Put another way, the system claims are no different from the method claims in substance; the method claims recite the abstract idea implemented on a generic computer, while the system claims recite a handful of generic computer components configured to implement the same idea. The claim does not amount to significantly more than the underlying abstract idea (Step 2B: NO). The claim is not eligible and should be rejected under 35 U.S.C. 101.

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

The following brief summaries are taken from decisions from the Supreme Court and the Federal Circuit in which claims were analyzed with respect to judicial exceptions to determine subject matter eligibility. Along with the examples in section III, these decisions demonstrate the various terms used by the courts to describe the exceptions and are provided simply to illustrate some of the different types of concepts found to fall within the exceptions. It should be noted that the courts' analyses in these decisions do not necessarily follow the eligibility framework explained in this Interim Eligibility Guidance as most of the cases were decided prior to Alice Corp. Therefore, instead of applying the eligibility analysis set forth in this Interim Eligibility Guidance to the facts of the decisions, a short description of the court's decision is provided for background

purposes only. When considering these decisions, it is important to remember that the mere presence of an exception does not necessarily render a claim ineligible.

Part A presents several decisions from the Supreme Court, Part B presents several decisions from the Federal Circuit from 2010 – 2014 that dealt with abstract ideas, and Part C presents decisions from the Federal Circuit relating to abstract ideas since the Alice Corp. decision. Although the very small set of decisions from the Federal Circuit since Alice Corp. have resulted in findings of ineligibility, it should be recognized that the Supreme Court did not create a per se excluded category of subject matter, such as software or business methods, nor did it impose any special requirements for eligibility of software or business methods.

A. Supreme Court Decisions

1. O'Reilly v. Morse (U.S. Reissue Patent No. RE 117)

> Claim 6. The claim was interpreted by the Supreme Court as a system of signs (signals) by closing a galvanic circuit rapidly for telegraphing, combined with machinery to record the signs.
>
> Claim 8. I do not propose to limit myself to the specific machinery, or parts of machinery, … the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed, for making or printing intelligible characters, signs, or letters, at any distances, being a new application of that power…

The claims are to the process of using electromagnetism to produce distinguishable signs for telegraphy, and in particular to print intelligible characters at any distance. While the

format of the claims is outdated, it can be seen that claim 6 recites the system of signs in combination with the machinery for recording, which was found eligible. In contrast, claim 8 recites the use of electromagnetism without limits on the machinery for recording, which was found ineligible. The discovery of electromagnetism, which is a natural phenomenon, is not patentable by itself.

2. Tilghman v. Proctor (U.S. Patent No. 11,766).

> The claim was interpreted by the Supreme Court as the process of subjecting to a high degree of heat a mixture continually kept up, of nearly equal quantities of fat and water in a convenient vessel strong enough to resist the effort of the mixture to convert itself into steam.

The claim is founded upon the chemical principle or scientific fact that the elements of neutral fat require that they be severally united with an atomic equivalent of water in order to separate from each other and become free. Although the claim recites the chemical union between the fatty elements and water, it is not directed to the mere principle. The claim is directed instead to a particular mode of bringing about the desired chemical union, i.e., by heating the water under such pressure that the water does not become steam, and accordingly was found eligible.

3. Mackay Radio & Telegraph Co. v. Radio Corp. of America (U.S. Patent No. 1,974,387)

> Claim 15. An antenna comprising a pair of relatively long conductors disposed with respect to each other at an angle substantially equal to twice $50.9(l/\lambda)^{-0.513}$ degrees, l being the length of the wire and λ the operating wave length in like units, and means in circuit with said antenna for exciting the conductors in phase opposition whereby standing waves of opposite instantaneous polarity are formed on the conductors throughout their length.

The claim is to an antenna system utilizing standing wave phenomena. To obtain the best directional radio propagation by a V type antenna, a mathematical formula is used to arrange the angle of the wires, their length, and the length of the wave propagated. The claim practically applies the mathematical formula to configure a particular antenna and thus was found eligible.

4. Gottschalk v. Benson

> Claim 8. The method of converting signals from binary coded decimal form into binary which comprises the steps of:
> (1) storing the binary coded decimal signals in a reentrant shift register,
> (2) shifting the signals to the right by at least three places, until there is a binary '1' in the second position of said register,
> (3) masking out said binary '1' in said second position of said register,
> (4) adding a binary '1' to the first position of said register,
> (5) shifting the signals to the left by two positions,
> (6) adding a '1' to said first position, and
> (7) shifting the signals to the right by at least three positions in preparation for a succeeding binary '1' in the second position of said register.

The claim recites a process for converting binary-coded-decimal (BCD) numerals into pure binary numerals. The procedures set forth in the claim are a generalized formulation

for programs to solve mathematical problems of converting one form of numerical representation to another. The mathematical procedures can be carried out in existing computers long in use or can be performed without a computer. The end use is unlimited. The process claim was found to be so abstract and sweeping that it covered both known and unknown uses of the BCD to pure binary conversion. The mathematical formula in the claim has no substantial practical application except in connection with a digital computer, and thus the court found the claim ineligible as it would in effect be a patent on the algorithm itself.

5. Bilski v. Kappos

> Claim 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.

The claim explains the basic concept of hedging, or protecting against risk. The court found that the concept of hedging is an unpatentable abstract idea, just like the algorithms at issue in Benson and Flook. A dependent claim that narrows the concept to a mathematical formula was similarly found to be an abstract idea. The other dependent claims are broad examples of how hedging can be used in commodities and energy

markets. Limiting an abstract idea to one field of use or adding token postsolution components does not make the concept patentable. The claims were found ineligible.

B. Abstract Idea Decisions from the Federal Circuit prior to Alice Corp. (2010 – 2014)

1. SiRF Technology v. ITC[46] (U.S. Patent No. 6,417,801)

> Claim 1. A method for calculating an absolute position of a GPS receiver and an absolute time of reception of satellite signals comprising:
> providing pseudoranges that estimate the range of the GPS receiver to a plurality of GPS satellites;
> providing an estimate of an absolute time of reception of a plurality of satellite signals;
> providing an estimate of a position of the GPS receiver;
> providing satellite ephemeris data;
> computing absolute position and absolute time using said pseudoranges by updating said estimate of an absolute time and the estimate of position of the GPS receiver.

GPS is a satellite navigation system comprising satellites orbiting the Earth that permits a GPS-enabled receiver to detect signals from at least four satellites and use that information to calculate its distance from each satellite and thus its precise position on Earth through trilateration. The claim sets forth the steps of calculating the absolute position, which is a mathematical concept. The court interpreted the claim such that the method could not be performed without a GPS receiver, noting that the preamble expressly states "calculating an absolute position of a GPS receiver" and that a GPS receiver is required to generate pseudoranges and to determine its position. With this

interpretation, the presence of the GPS receiver in the claim places a meaningful limit on the scope of the claim. It is essential to the operation of the claimed method and plays a significant part in permitting the claimed method to be performed. As such, although performance of the claim requires calculations, the claim was found eligible.

2. Research Corp. Tech. v. Microsoft Corp.[47] (U.S. Patent No. 5,111,310)

> Claim 1. A method for the halftoning of gray scale images by utilizing a pixel-by-pixel comparison of the image against a blue noise mask in which the blue noise mask is comprised of a random non-deterministic, non-white noise single valued function which is designed to produce visually pleasing dot profiles when thresholded at any level of said gray scale images.

The claim is to digital image halftoning. Halftoning techniques allow computers to present many shades and color tones with a limited number of pixels, which allows computer displays and printers to render an approximation of an image by using fewer colors or shades of gray than the original image. One method of generating a digital halftoned image is called "thresholding" that uses a two-dimensional array called a "mask." The claimed method incorporates algorithms and formulas that control the masks and halftoning, but apply them in a technique that improves the generated digital halftoned image. The invention presents functional and palpable applications in the field of computer technology with specific applications or improvements to technologies in the

[46] SiRF Tech. v. ITC, 601 F.3d 1319 (Fed. Cir. 2010).
[47] Research Corp. Tech. v. Microsoft Corp., 627 F.3d 859 (Fed. Cir. 2010).

marketplace. So, although the claimed method uses algorithms and formulas, the claim was found eligible.

3. Dealertrack Inc. v. Huber (U.S. Patent No. 7,181,427)

> Claim 1. A computer aided method of managing a credit application, the method comprising the steps of:
> [A] receiving credit application data from a remote application entry and display device;
> [B] selectively forwarding the credit application data to remote funding source terminal devices;
> [C] forwarding funding decision data from at least one of the remote funding source terminal devices to the remote application entry and display device;
> [D] wherein the selectively forwarding the credit application data step further comprises:
>
> > [D1] sending at least a portion of a credit application to more than one of said remote funding sources substantially at the same time;
> > [D2] sending at least a portion of a credit application to more than one of said remote funding sources sequentially until a finding source returns a positive funding decision;
> > [D3] sending at least a portion of a credit application to a first one of said remote funding sources, and then, after a predetermined time, sending to at least one other remote funding source, until one of the finding sources returns a positive funding decision or until all funding sources have been exhausted; or,
> > [D4] sending the credit application from a first remote funding source to a second remote finding source if the first funding source declines to approve the credit application.

The court reduced the claim to its most basic concept which was characterized as receiving data from one source (step A), selectively forwarding the data (step B, performed according to step D), and forwarding reply data to the first source (step C). This basic concept of processing information through a clearinghouse was found to be an abstract idea, similar to Bilski's basic concept of hedging. The court held that simply

adding a "computer-aided" limitation to a claim covering an abstract concept, without more, does not sufficiently limit the claim. The claim was found ineligible.

4. SmartGene, Inc. v. Advanced Biological Laboratories, SA (U.S. Patent No. 6,081,786)

> Claim 1. A method for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition, said method comprising:
> (a) providing patient information to a computing device comprising:
> a first knowledge base comprising a plurality of different therapeutic treatment regimens for said disease or medical condition;
> a second knowledge base comprising a plurality of expert rules for evaluating and selecting a therapeutic treatment regimen for said disease or medical condition;
> a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens; and
> (b) generating in said computing device a ranked listing of available therapeutic treatment regimens for said patient; and
> (c) generating in said computing device advisory information for one or more therapeutic treatment regimens in said ranked listing based on said patient information and said expert rules.

The claims set forth the steps of comparing new and stored information and using rules to identify medical options. Claim 1 does no more than call on a "computing device" with basic functionality for comparing stored and input data and rules, to do what doctors do routinely. The court concluded that these are familiar mental steps performed by or with a computer, and as such the claim was found ineligible.

5. Cyberfone Systems v. CNN Interactive Group (U.S. Patent No. 8,019,060)

> Claim 1. A method, comprising:
> obtaining data transaction information entered on a telephone from a single transmission from said telephone;
> forming a plurality of different exploded data transactions for the single transmission, said plurality of different exploded data transaction indicative of a single data transaction, each of said exploded data transactions having different data that is intended for a different destination that is included as part of the exploded data transactions, and each of said exploded data transactions formed based on said data transaction information from said single transmission, so that different data from the single data transmission is separated and sent to different destinations; and
> sending said different exploded data transactions over a channel to said different destinations, all based on said data transaction information entered in said single transmission.

Using categories to organize, store, and transmit information is well-established. Here, the well-known concept of categorical data storage, i.e., the idea of collecting information in classified form, then separating and transmitting that information according to its classification, is an abstract idea. The claim was found ineligible.

C. Abstract Idea Decisions from the Federal Circuit since Alice Corp.

1. Digitech Image Tech., LLC v. Electronics for Imaging, Inc. (U.S. Patent No. 6,128,415)

> Claim 10. A method of generating a device profile that describes properties of a device in a digital image reproduction system for capturing, transforming or rendering an image, said method comprising:
> generating first data for describing a device dependent transformation of color information content of the image to a device independent color space through use of measured chromatic stimuli and device response characteristic functions;
> generating second data for describing a device dependent transformation of spatial information content of the image in said device independent

color space through use of spatial stimuli and device response characteristic functions; and
combining said first and second data into the device profile.

The court found the claim to be an abstract idea because it describes a process of organizing information through mathematical correlations and is not tied to a specific structure or machine. The claim recites the process of taking two data sets and combining them into a single data set, the device profile. The two data sets are generated by taking existing information—i.e., measured chromatic stimuli, spatial stimuli, and device response characteristic functions—and organizing this information into a new form. The claim language does not expressly tie the method to an image processor. It generically recites a process of combining two data sets into the device profile; it does not claim the processor's use of that profile in the capturing, transforming, or rendering of a digital image. Without additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible. All of the claims were found ineligible.

2. Planet Bingo, LLC v. VKGS LLC (U.S. Patent No. 6,398,646)

Claim 1. A system for managing a game of Bingo which comprises:
(a) a computer with a central processing unit (CPU) and with a memory and with a printer connected to the CPU;
(b) an input and output terminal connected to the CPU and memory of the computer; and
(c) a program in the computer enabling:
(i) input of at least two sets of Bingo numbers which are preselected by a player to be played in at least one selected game of Bingo in a future period of time;

> (ii) storage of the sets of Bingo numbers which are preselected by the player as a group in the memory of the computer;
> (iii) assignment by the computer of a player identifier unique to the player for the group having the sets of Bingo numbers which are preselected by the player wherein the player identifier is assigned to the group for multiple sessions of Bingo;
> (iv) retrieval of the group using the player identifier;
> (v) selection from the group by the player of at least one of the sets of Bingo numbers preselected by the player and stored in the memory of the computer as the group for play in a selected game of Bingo in a specific session of Bingo wherein a number of sets of Bingo numbers selected for play in the selected game of Bingo is less than a total number of sets of Bingo numbers in the group;
> (vi) addition by the computer of a control number for each set of Bingo numbers selected for play in the selected game of Bingo;
> (vii) output of a receipt with the control number, the set of Bingo numbers which is preselected and selected by the player, a price for the set of Bingo numbers which is preselected, a date of the game of Bingo and optionally a computer identification number; and
> (viii) output for verification of a winning set of Bingo numbers by means of the control number which is input into the computer by a manager of the game of Bingo.

The court found the claims to be directed to the abstract idea of solving a tampering problem and also minimizing other security risks during bingo ticket purchases. The claims relate to managing a bingo game while allowing a player to repeatedly play the same sets of numbers in multiple sessions. Managing the game of bingo consists solely of mental steps which can be carried out by a human using pen and paper. The claims do not impose any requirements that would make the invention impossible to carry out manually. Although not drawn to the same subject matter at issue in Bilski and Alice Corp., the court found managing a game of bingo to be similar to the kind of organizing human activity at issue in Alice Corp. The claims recite a generic computer implementation of the abstract idea and a program that is used for the generic functions of storing, retrieving, and verifying a chosen set of bingo numbers against a winning set

of bingo numbers. There is no inventive concept sufficient to transform the claimed subject matter into a patent-eligible application. The court found no meaningful distinction between the method and system claims. All of the claims were found ineligible.

3. buySAFE, Inc. v. Google, Inc. (U.S. Patent No. 7,644,019)

> Claim 1. A method, comprising:
> receiving, by at least one computer application program running on a computer of a safe transaction service provider, a request from a first party for obtaining a transaction performance guaranty service with respect to an online commercial transaction following closing of the online commercial transaction;
> processing, by at least one computer application program running on the safe transaction service provider computer, the request by underwriting the first party in order to provide the transaction performance guaranty service to the first party,
> wherein the computer of the safe transaction service provider offers, via a computer network, the transaction performance guaranty service that binds a transaction performance guaranty to the online commercial transaction involving the first party to guarantee the performance of the first party following closing of the online commercial transaction.
>
> Claim 14. The method according to claim 1, wherein the transaction performance guaranty is provided in one form of: a surety bond; a specialized bank guaranty; a specialized insurance policy; and a safe transaction guaranty provided by the safe transaction service provider.

Relying on Bilski in which an abstract idea was found in certain arrangements involving contractual relations, the court found the claims to be squarely about creating a contractual relationship—a "transaction performance guaranty"—that is beyond question of ancient lineage. The claims' invocation of computers adds no inventive concept, with the computer functionality being generic. The transactions being performed online, at

best, limits the use of the abstract guaranty idea to a particular technological environment. Although, dependent claim 14 narrows the abstract idea to particular types of relationships, that does not change the analysis because it does not make the idea non-abstract. The claims to the computer readable medium encoded with instructions to carry out the method were treated in the same way. All of the claims were found ineligible.

4. Ultramercial, LLC v. Hulu, LLC and WildTangent (U.S. Patent No. 7,346,545)

Claim 1: A method for distribution of products over the Internet via a facilitator, said method comprising the steps of:
a first step of receiving, from a content provider, media products that are covered by intellectual-property rights protection and are available for purchase, wherein each said media product being comprised of at least one of text data, music data, and video data;
a second step of selecting a sponsor message to be associated with the media product, said sponsor message being selected from a plurality of sponsor messages, said second step including accessing an activity log to verify that the total number of times which the sponsor message has been previously presented is less than the number of transaction cycles contracted by the sponsor of the sponsor message;
a third step of providing the media product for sale at an Internet website;
a fourth step of restricting general public access to said media product;
a fifth step of offering to a consumer access to the media product without charge to the consumer on the precondition that the consumer views the sponsor message;
a sixth step of receiving from the consumer a request to view the sponsor message, wherein the consumer submits said request in response to being offered access to the media product;
a seventh step of, in response to receiving the request from the consumer, facilitating the display of a sponsor message to the consumer;
an eighth step of, if the sponsor message is not an interactive message, allowing said consumer access to said media product after said step of facilitating the display of said sponsor message;
a ninth step of, if the sponsor message is an interactive message, presenting at least one query to the consumer and allowing said consumer access to said media product after receiving a response to said at least one query;
a tenth step of recording the transaction event to the activity log, said tenth step including updating the total number of times the sponsor message has been presented; and
an eleventh step of receiving payment from the sponsor of the sponsor message displayed.

Using the Alice Corp. framework, the court first determined whether the claims at issue are directed to a patent-ineligible concept. The court found that the ordered combination of the eleven steps recites "an abstraction – an idea, having no particular concrete or tangible form" noting that the majority of limitations describe only the abstract idea of showing an advertisement before delivering content. The court then turned to the next step of the analysis to determine whether the claims do significantly more than simply describe the abstract method. The court explained that consulting and updating an activity log represent insignificant "data-gathering steps," restricting public access represents only insignificant "[pre]-solution activity," and narrowing the idea to the Internet is an attempt to limit the use of the abstract idea "to a particular technological environment." Viewed both individually and as an ordered combination, the claimed steps were found insufficient to supply an inventive concept because the steps are conventional and specified at a high level of generality. The court concluded that the claim limitations do not transform the abstract idea that they recite into patent-eligible subject matter because "the claims simply instruct the practitioner to implement the abstract idea with routine, conventional activity." All of the claims were found ineligible.

5. DDR Holdings, LLC v. Hotels.com, L.P. (U.S. Patent No. 7,818,399)

> Claim 19: A system useful in an outsource provider serving web pages offering commercial opportunities, the system comprising:
> (a) a computer store containing data, for each of a plurality of first web pages, defining a plurality of visually perceptible elements, which visually perceptible elements correspond to the plurality of first web pages;
> (i) wherein each of the first web pages belongs to one of a plurality of web page owners;
> (ii) wherein each of the first web pages displays at least one active link associated with a commerce object associated with a buying opportunity of a selected one of a plurality of merchants; and

(iii) wherein the selected merchant, the outsource provider, and the owner of the first web page displaying the associated link are each third parties with respect to one other;
(b) a computer server at the outsource provider, which computer server is coupled to the computer store and programmed to:
(i) receive from the web browser of a computer user a signal indicating activation of one of the links displayed by one of the first web pages;
(ii) automatically identify as the source page the one of the first web pages on which the link has been activated;
(iii) in response to identification of the source page, automatically retrieve the stored data corresponding to the source page; and
(iv) using the data retrieved, automatically generate and transmit to the web browser a second web page that displays: (A) information associated with the commerce object associated with the link that has been activated, and (B) the plurality of visually perceptible elements visually corresponding to the source page.

The court found the claim patent eligible under the Alice Corp. framework. First, the court noted that, while in some instances abstract ideas are plainly identifiable and divisible from generic computer limitations recited by the remainder of a claim, in this case, identifying the precise nature of the abstract idea is not as straightforward. The court considered several proposed characterizations of the abstract idea, including "'making two web pages look the same,' 'syndicated commerce on the computer using the Internet' and 'making two e-commerce web pages look alike by using licensed trademarks, logos, color schemes and layouts,'" and "that an online merchant's sales can be increased if two web pages have the same 'look and feel.'" The court did not clearly indicate whether the claim was directed to one or more of these proposed abstract ideas, but stated that "under any of these characterizations of the abstract idea, the '399 patent's claims satisfy Mayo/Alice step two."

The court then explained its analysis of the second Mayo/Alice step, where it determined that the claim amounted to an inventive concept and thus was patent eligible. In particular, the claim addresses the problem of retaining website visitors from being diverted from a host's website to an advertiser's website, for which "the claimed solution is necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks." The claim includes additional elements including "1) stor[ing] 'visually perceptible elements' corresponding to numerous host websites in a database, with each of the host websites displaying at least one link associated with a product or service of a third-party merchant, 2) on activation of this link by a website visitor, automatically identif[ying] the host, and 3) instruct[ing] an Internet web server of an 'outsource provider' to construct and serve to the visitor a new, hybrid web page that merges content associated with the products of the third-party merchant with the stored 'visually perceptible elements' from the identified host website." The court held that, unlike in Ultramercial, the claim does not generically recite "use the Internet" to perform a business practice, but instead recites a specific way to automate the creation of a composite web page by an outsource provider that incorporates elements from multiple sources in order to solve a problem faced by websites on the Internet. Therefore, the court held that the claim is patent eligible.

Guidelines for Written Comments

It would be helpful to the USPTO if written comments include information about: (1) the name and affiliation of the individual responding; and (2) an indication of whether comments offered represent views of the respondent's organization or are the

respondent's personal views. Information provided in response to this request for comments will be made part of a public record and may be available via the Internet. In view of this, parties should not submit information that they do not wish to be publicly disclosed or made electronically accessible. Parties who would like to rely on confidential information to illustrate a point are requested to summarize or otherwise submit the information in a way that will permit its public disclosure.

Dated: December 10, 2014.

Michelle K. Lee,
Deputy Under Secretary of Commerce for Intellectual Property and
Deputy Director of the United States Patent and Trademark Office.

[FR Doc. 2014-29414 Filed 12/15/2014 at 8:45 am; Publication Date: 12/16/2014]

Nature-Based Products

The following examples should be used in conjunction with the 2014 Interim Eligibility Guidance. They replace the examples issued with the March 2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products and related training. As the examples are intended to be illustrative only, they should be interpreted based on fact patterns set forth below. Other fact patterns may have different eligibility outcomes.

1. Gunpowder and Fireworks: Product Claims That Are Not Directed To An Exception

This example illustrates the application of the markedly different characteristics analysis to a nature-based product produced by combining multiple components (claim 1), and also provides a sample of a claimed product that when viewed as a whole is not nature-based, and thus is not subjected to the markedly different characteristics analysis in order to determine that the claim is not directed to an exception (claim 2).

Claims:

1. Gunpowder comprising: an intimate finely-ground mixture of 75% potassium nitrate, 15% charcoal and 10% sulfur.
2. A fountain-style firework comprising: (a) a sparking composition, (b) calcium chloride, (c) the gunpowder of claim 1, (d) a cardboard body having a first compartment containing the sparking composition and the calcium chloride and a second compartment containing the gunpowder, and (e) a plastic ignition fuse having one end extending into the second compartment and the other end extending out of the cardboard body.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. Both claims are directed to a statutory category, *e.g.*, a composition of matter or manufacture (*Step 1: YES*).

Claim 1: Eligible. Because the claim is a nature-based product, *i.e.*, a combination of three naturally occurring substances (potassium nitrate, charcoal and sulfur), the nature-based product (the combination) is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. In this case, there is no naturally occurring counterpart to the claimed combination (the components do not occur together in nature), so the combination is compared to the individual components as they occur in nature. None of the three claimed substances are explosive in nature. When the substances are finely-ground and intimately mixed in the claimed ratio, however, the claimed combination is explosive upon ignition. This explosive property of the claimed combination is markedly different from the non-explosive properties of the substances by themselves in nature. Accordingly, the claimed combination has markedly different characteristics, and is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO)*, and qualifies as eligible subject matter.

Claim 2: Eligible. Although the claim recites two nature-based products (calcium chloride and gunpowder), analysis of the claim as a whole indicates that the claim is focused on the assembly of components that together form the firework, and not the nature-based products. Thus, it is not necessary to apply the markedly different characteristics analysis in order to conclude that the claim is not directed to an exception (*Step 2A: NO)*. The claim qualifies as eligible subject matter.

2. Pomelo Juice: Process Claim That Is Directed To An Exception And Product Claim That Is Not Directed To An Exception

This example illustrates the eligibility analysis of a process (claim 1) that focuses on a nature-based product and a product (claim 2) that is nature-based but is not directed to an exception because it has markedly different characteristics from its naturally occurring counterpart.

Background: The pomelo tree (*Citrus maxima*) is a naturally occurring tree that is native to South and Southeast Asia. Pomelo fruit is often eaten raw or juiced, and has a mild grapefruit-like flavor. Naturally occurring pomelo juice spoils over the course of a few days even when refrigerated, due to the growth of bacteria that are naturally present in the juice. The specification indicates that suitable preservatives for fruit juices are known in the art, and include naturally occurring preservatives such as vitamin E, and non-naturally occurring preservatives such as preservative X. The specification defines an "effective amount" of these preservatives as an amount sufficient to prevent juice from spoiling for at least three weeks, *e.g.*, by retarding the growth of bacteria in the juice.

Claims:

1. A method comprising providing a pomelo fruit.

2. A beverage composition comprising pomelo juice and an effective amount of an added preservative.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. All of the claims are directed to a statutory category, *e.g.*, a process or composition of matter (*Step 1: YES*).

Claim 1: Ineligible. Although the claim is a process claim, it has been drafted such that there is no difference in substance from a product claim to the pomelo fruit itself. Accordingly, this process claim is focused on the pomelo fruit *per se* (a nature-based product), and must be analyzed for markedly different characteristics, to determine whether the claimed pomelo fruit is a "product of nature" exception. There is no indication in the specification that the claimed fruit has any characteristics (structural, functional, or otherwise) that are different from the naturally occurring fruit provided by pomelo trees. Thus, the claimed fruit does not have markedly different characteristics from what occurs in nature, and is a "product of nature" exception. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Because the claim does not include any additional features that could add significantly more to the exception (*Step 2B: NO*), the claim does not qualify as eligible subject matter, and should be rejected under 35 U.S.C. § 101.

Claim 2: Eligible. Because the claim is a nature-based product, *i.e.*, a combination of a naturally occurring substance (pomelo juice) with an added preservative, the nature-based combination is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. In this case, there is no naturally occurring counterpart to the claimed combination, so the combination is compared to the individual components as they occur in nature. The specification indicates that the preservative can be natural or non-natural in origin, but that regardless of its origin, when an effective amount of preservative is mixed with the pomelo juice, the preservative affects the juice so that it spoils much more slowly (spoils in a few weeks) than the naturally occurring juice by itself (spoils in a few days). This property (slower spoiling) of the claimed combination is markedly different from properties of the juice by itself in nature. Accordingly, the claimed combination has markedly different characteristics, and is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

3. Amazonic Acid, Pharmaceutical Compositions, & Methods of Treatment

This example illustrates the application of the markedly different characteristics analysis to single-element product claims (claims 1, 2 and 3) and to a product-by-process claim (claim 4). It also demonstrates that changes in chemical structure (claims 2 and 3), physical form (claim 5), or chemical/physical properties (claim 6), as compared to a product's natural counterpart can demonstrate markedly different characteristics. Additionally, this example provides samples of claimed processes that when viewed as a whole are not directed to a nature-based product, and thus are not subjected to the markedly different characteristics analysis in order to determine that the claim is not directed to an exception (claims 7 and 8).

Nature-Based Products

Background: The Amazonian cherry tree is a naturally occurring tree that grows wild in the Amazon basin region of Brazil. The leaves of the Amazonian cherry tree contain a chemical that is useful in treating breast and colon cancers. Many have tried and failed to isolate the cancer-fighting chemical from the leaves. Applicant has successfully purified the cancer-fighting chemical from the leaves and has named it amazonic acid. The purified amazonic acid is structurally and functionally identical to the amazonic acid in the leaves. Applicant has created two derivatives of amazonic acid in the laboratory. The first derivative (called 5-methyl amazonic acid), is structurally different from amazonic acid because a hydrogen has been replaced with a methyl group, and is functionally different because it stimulates the growth of hair in addition to treating cancer. The second derivative (called deoxyamazonic acid), was created by removing a hydroxyl group from amazonic acid and replacing it with a hydrogen. Applicant has not identified any functional difference between deoxyamazonic acid and amazonic acid.

Amazonic acid is absorbed through the lining of the human stomach and is rapidly metabolized by the body. It is also insoluble in water. Applicants disclose an example of a solid pharmaceutical composition demonstrating that when a core of amazonic acid is enveloped by a layer of a natural polymeric material, the resulting manufacture does not release the amazonic acid until it reaches the colon. This colonic release greatly improves the bioavailability of amazonic acid, and is particularly advantageous in the treatment of colon cancer. The specification defines “natural polymeric material” as being a naturally occurring polymer that is not easily digestible by human enzymes, so that it passes through most of the human digestive system intact until it reaches the colon. Specific disclosed examples are shellac and inulin. Applicants disclose an example of an aqueous composition, in which they were able to achieve a stable solution of amazonic acid in water by including a solubilizing agent in the solution. The solubilizing agent can be a naturally occurring product such as a sugar or polyol, or it can be a non-naturally occurring product such as a polysorbate surfactant.

Claims:

1. Purified amazonic acid.
2. Purified 5-methyl amazonic acid.
3. Deoxyamazonic acid.
4. A composition comprising an acid produced by a process which comprises: providing amazonic acid; and replacing the hydroxyl group of the amazonic acid with a hydrogen.
5. A pharmaceutical composition comprising: a core comprising amazonic acid; and a layer of natural polymeric material enveloping the core.
6. A stable aqueous composition comprising: amazonic acid; and a solubilizing agent.
7. A method of treating colon cancer, comprising: administering a daily dose of purified amazonic acid to a patient suffering from colon cancer for a period of time from 10 days to 20 days, wherein said daily dose comprises about 0.75 to about 1.25 teaspoons of amazonic acid.
8. A method of treating breast or colon cancer, comprising: administering an effective amount of purified amazonic acid to a patient suffering from breast or colon cancer.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. All of the claims are directed to a statutory category, *e.g.*, a composition of matter or process (*Step 1: YES*). Because claims 1-6 are nature-based products (*e.g.*, amazonic acid, 5-methyl amazonic acid, or deoxyamazonic acid), the markedly different characteristics analysis is used to determine if the nature-based products are exceptions. Although claims 7-8 recite nature-based products (amazonic acid), a full eligibility analysis of these claims is not needed because the claims clearly do not seek to tie up all practical uses of the nature-based products.

Nature-Based Products

Claim 1: Ineligible. Although applicant has discovered that amazonic acid naturally occurs in the leaves of the Amazonian cherry tree, this discovery does not, by itself, render amazonic acid patent eligible. *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. __, 133 S. Ct. 2107, 2117 (2013) ("*Myriad*"). Instead, the claimed acid is analyzed to determine if separating the acid from its surrounding material in the leaf has resulted in the purified amazonic acid having markedly different characteristics from its naturally occurring counterpart. Based on the limited background information, there is no indication that purified amazonic acid has any characteristics (structural, functional, or otherwise) that are different from naturally occurring amazonic acid. The claim therefore encompasses amazonic acid that is structurally and functionally identical to naturally occurring amazonic acid. Because there is no difference between the claimed and naturally occurring acid, the claimed acid does not have markedly different characteristics from what occurs in nature, and thus is a "product of nature" exception. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Because the claim does not include any additional features that could add significantly more to the exception (*Step 2B: NO*), the claim does not qualify as eligible subject matter, and should be rejected under 35 U.S.C. § 101.

Claim 2: Eligible. The claimed 5-methyl amazonic acid has a different structural characteristic than amazonic acid (its chemical structure is different due to the addition of the 5-methyl group). Because 5-methyl amazonic acid is a unique molecule that is distinct from, and does not prevent others from using, naturally occurring amazonic acid, its different structural characteristic rises to the level of a marked difference. Accordingly, the claimed 5-methyl amazonic acid is not a "product of nature" exception. This conclusion is bolstered by the fact that the different structural characteristic has resulted in a different functional characteristic (the stimulation of hair growth). Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 3: Eligible. The claimed deoxyamazonic acid has a different structural characteristic from amazonic acid (its chemical structure is different due to the removal of a hydroxyl group). Based on the limited background information, this change in structure has not resulted in any different functional characteristics. However, because deoxyamazonic acid is a unique molecule that is distinct from, and does not prevent others from using, naturally occurring amazonic acid, its different structural characteristic rises to the level of a marked difference. Accordingly, the claimed deoxyamazonic acid is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 4: Eligible. During examination, a product-by-process claim is not limited to manipulations of the recited steps, but instead is only limited to the structure implied by the steps. In this case, the specification describes that removing a hydroxyl group from amazonic acid and replacing it with a hydrogen results in deoxyamazonic acid. Thus, the acid produced by the claimed process steps is deoxyamazonic acid. As explained with respect to claim 3, deoxyamazonic acid has markedly different characteristics than naturally occurring amazonic acid, and is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 5: Eligible. The claim is limited to a particular pharmaceutical composition having two naturally occurring substances physically joined together into a non-natural structure (core of amazonic acid surrounded by a layer of natural polymeric material). The claimed composition thus is structurally different from the naturally occurring substances, and this structural difference results in the claimed composition having different functional characteristics *in vivo* (*e.g.*, amazonic acid is not released until the composition reaches the colon, due to the relative indigestibility of the natural polymeric material, thus increasing the bioavailability of the amazonic acid) than the naturally occurring substances by themselves. These different structural and functional characteristics rise to the level of a marked difference, and accordingly the claimed composition is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 6: Eligible. In nature, amazonic acid is insoluble in water. As explained in the specification, however, when amazonic acid is combined with a solubilizing agent, it becomes soluble in water and forms a stable solution. This changed property (solubility) between amazonic acid as a part of the claimed stable aqueous composition and amazonic acid in nature is a marked difference. Accordingly, the claimed composition has markedly different characteristics, and is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 7: Eligible. Although the claim recites a nature-based product (amazonic acid), analysis of the claim as a whole indicates that the claim is focused on a process of practically applying the product to treat a particular disease (colon cancer), and not on the product *per se*. Thus, it is not necessary to apply the markedly different characteristics analysis in order to conclude that the claim is not directed to an exception (*Step 2A: NO)*. The claim qualifies as eligible subject matter.

Claim 8: Eligible. Although the claim recites a nature-based product (amazonic acid), analysis of the claim as a whole indicates that the claim is focused on a process of practically applying the product to treat a particular disease (breast or colon cancer), and not on the product *per se*. Thus, it is not necessary to apply the markedly different characteristics analysis in order to conclude that the claim is not directed to an exception (*Step 2A: NO)*. The claim qualifies as eligible subject matter.

4. Purified Proteins

This example illustrates that changes in physical/chemical structure (claims 2-5) as compared to a product's natural counterpart can demonstrate markedly different characteristics, whether or not accompanied by changes in biological/pharmacological function or chemical/physical properties.

Background: Newly discovered *Streptomyces arizoneus* bacteria produce Antibiotic L, which exhibits antibiotic activity in nature (*e.g.*, it kills other bacterial species in its natural environment). Naturally occurring Antibiotic L is a protein that occurs in the form of hexagonal-pyramidal crystals (each crystal has the shape of a six-sided pyramid) that are stored inside the bacteria. The specification describes several processes that yield Antibiotic L having the same hexagonal-pyramidal crystal form as naturally occurring Antibiotic L. The specification also discloses a process that yields purified Antibiotic L in the form of tetrahedral crystals (each crystal has the shape of a tetrahedron or triangular pyramid). The specification discloses that naturally occurring Antibiotic L has the amino acid sequence of SEQ ID NO: 2, and has a bacillosamine N-glycan on residue 49. In the specification, applicants describe recombinant yeast that are able to synthesize Antibiotic L (naturally occurring yeast cannot synthesize Antibiotic L or bacillosamine). Purified Antibiotic L expressed by these recombinant yeast has a high mannose (instead of a bacillosamine) N-glycan on residue 49, and has lower immunogenicity to humans and a different half-life *in vivo* than naturally occurring Antibiotic L. The specification defines "purified Antibiotic L" as only being either Antibiotic L in the tetrahedral crystal form or Antibiotic L having a high mannose N-glycan on residue 49.

Applicants disclose substitution modifications of Antibiotic L, *e.g.*, peptides having one or more amino acids substituted with different amino acids relative to SEQ ID NO: 2. No substitution modifications of Antibiotic L are known to occur in nature. Some of the modifications result in altering the function of the peptide, for example by increasing its ability to penetrate the cell membrane of a target organism. The modified peptides have 90% or greater identity to SEQ ID NO: 2.

Claims:

1. Antibiotic L.
2. Purified Antibiotic L.
3. The Antibiotic L of claim 1, which is in a tetrahedral crystal form.
4. The Antibiotic L of claim 1, which is expressed by recombinant yeast.

5. A purified antibiotic comprising an amino acid sequence that has at least 90% identity to SEQ ID NO: 2 and contains at least one substitution modification relative to SEQ ID NO: 2.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. Because all of the claims are directed to a statutory category, *e.g.*, a composition of matter (*Step 1: YES*), and are nature-based products (Antibiotic L or a derivative thereof), the markedly different characteristics analysis is used to determine if the nature-based products are exceptions.

Claim 1: Ineligible. As described in the specification, some Antibiotic L produced by the applicants is in its naturally occurring hexagonal-pyramidal crystal form, while other Antibiotic L is in a non-natural form, *e.g.*, tetrahedral crystals. The claim thus encompasses antibiotic that is identical to the natural antibiotic, and antibiotic that is changed. Because there is no difference in characteristics (structural, functional, or otherwise) between the claimed and naturally occurring antibiotic for at least some of the embodiments encompassed by the claim, the claimed Antibiotic L does not have markedly different characteristics from what exists in nature, and thus is a "product of nature" exception. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Because the claim does not include any additional features that could add significantly more to the exception (*Step 2B: NO*), the claim does not qualify as eligible subject matter, and should be rejected under 35 U.S.C. § 101.

Claim 2: Eligible. Based on the specification's definition of purified Antibiotic L, the claim is limited to Antibiotic L in the form of tetrahedral crystals or having a high-mannose N-glycan on residue 49. The claim does not encompass naturally occurring Antibiotic L (which forms hexagonal-pyramidal crystals, and has a bacillosamine N-glycan on residue 49). The claimed antibiotic has particular structural/physical characteristics that are different from the naturally occurring antibiotic (*e.g.*, different crystalline form or different N-glycan). The person of ordinary skill in the art would understand that these structural differences may result in the claimed antibiotic having different functional characteristics (*e.g.*, different powder flow behavior or lower immunogenicity and different half-life) than the naturally occurring antibiotic. These differences rise to the level of a marked difference, and thus the claimed antibiotic is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 3: Eligible. The claim is limited to Antibiotic L in the form of tetrahedral crystals, and does not encompass the naturally occurring hexagonal-pyramidal crystals. Although the claimed antibiotic is chemically unchanged from nature, the claimed antibiotic has particular structural/physical characteristics that are different from the naturally occurring antibiotic (*e.g.*, different crystalline form). The person of ordinary skill in the art would understand that these structural differences may result in the claimed antibiotic having different functional characteristics (*e.g.*, powder flow behavior) than the naturally occurring antibiotic. These differences rise to the level of a marked difference, and thus the claimed antibiotic is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 4: Eligible. During examination, a product-by-process claim is not limited to manipulations of the recited steps, but instead is only limited to the structure implied by the steps. In this case, the specification describes that Antibiotic L produced by recombinant yeast has a different structure (high-mannose N-glycan) than the natural antibiotic (bacillosamine N-glycan). The claim is therefore limited to a structurally different Antibiotic L having a high-mannose N-glycan. This structural difference results in a change to the properties of the claimed antibiotic (lower immunogenicity and different half-life than the natural antibiotic). These differences rise to the level of a marked difference, and thus the claimed antibiotic is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 5: Eligible. The claim is limited to peptides in which the amino acid sequence has at least 90% identity to SEQ ID NO: 2, but has been changed to contain at least one non-naturally occurring substitution modification relative to SEQ ID NO: 2. All of the claimed peptides have different structural characteristics (*e.g.*, one or more amino acids have been changed relative to the natural sequence). Some of the claimed peptides may have different functional characteristics, but at least for some conservative modifications there may be no observable functional difference. Because the structural differences between the claimed peptides and their natural counterparts are enough to ensure that the claim is not improperly tying up the future use of naturally occurring Antibiotic L, they rise to the level of a marked difference, and thus the claimed antibiotic is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

5. Genetically Modified Bacterium

This example illustrates that a naturally occurring product that is unchanged from its natural state does not have markedly different characteristics (claim 1), but that changes in biological function between a claimed product and its natural counterpart can demonstrate markedly different characteristics (claim 2).

Background: Stable energy-generating plasmids that provide hydrocarbon degradative pathways exist within certain bacteria in nature. Different plasmids provide the ability to degrade different hydrocarbons, *e.g.*, one plasmid provides the ability to degrade camphor, and a different plasmid provides the ability to degrade octane. *Pseudomonas* bacteria are naturally occurring bacteria. Naturally occurring *Pseudomonas* bacteria containing one stable energy-generating plasmid and capable of degrading a single type of hydrocarbon are known. There are no known *Pseudomonas* bacteria in nature that contain more than one stable energy-generating plasmid. In the specification, applicant discloses genetically modifying a *Pseudomonas* bacterium to include more plasmids than are found in a single naturally occurring *Pseudomonas* bacterium.

Claims:

1. A stable energy-generating plasmid, which provides a hydrocarbon degradative pathway.
2. A bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. Because both claims are directed to a statutory category, *e.g.*, a manufacture or composition of matter (*Step 1: YES*), and are nature-based products (plasmid or bacterium), the markedly different characteristics analysis is used to determine if the nature-based products are exceptions.

Claim 1: Ineligible. Based on the limited background information, there is no indication that the claimed plasmid has any characteristics (structural, functional, or otherwise) that are different from naturally occurring energy-generating plasmids. Because there is no difference between the claimed and naturally occurring plasmid, the claimed plasmid does not have markedly different characteristics, and thus is a "product of nature" exception. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Because the claim does not include any additional features that could add significantly more to the exception (*Step 2B: NO*), the claim does not qualify as eligible subject matter, and should be rejected under 35 U.S.C. § 101.

Claim 2: Eligible. The claimed bacterium has a different functional characteristic from naturally occurring *Pseudomonas* bacteria, *i.e.*, it is able to degrade at least two different hydrocarbons as compared to naturally occurring *Pseudomonas* bacteria that can only degrade a single hydrocarbon. The claimed bacterium also has a different structural characteristic, *i.e.*, it was genetically modified to include more plasmids than are found in a single naturally occurring *Pseudomonas* bacterium. The different functional and structural characteristics rise to the level of a marked difference, and accordingly the

claimed bacterium is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

The bacterium of claim 2 was held to be patent-eligible subject matter in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Recently, the Supreme Court looked back to this claim as an example of a nature-based product that is patent-eligible because it has markedly different characteristics than naturally occurring bacteria, as explained in *Myriad*, 133 S. Ct. at 2116-17:

> In *Chakrabarty*, scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil. 447 U. S., at 305, 100 S. Ct. 2204, 65 L. Ed. 2d 144, and n. 1. The Court held that the modified bacterium was patentable. It explained that the patent claim was "not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter--a product of human ingenuity 'having a distinctive name, character [and] use.'" *Id.*, at 309-310, 100 S. Ct. 2204, 65 L. Ed. 2d 144 (quoting *Hartranft v. Wiegmann*, 121 U. S. 609, 615, 7 S. Ct. 1240, 30 L. Ed. 1012 (1887); alteration in original). The *Chakrabarty* bacterium was new "with markedly different characteristics from any found in nature," 447 U. S., at 310, 100 S. Ct. 2204, 65 L. Ed. 2d 144, due to the additional plasmids and resultant "capacity for degrading oil."

6. Bacterial Mixtures

This example illustrates the application of the markedly different characteristics analysis to nature-based product claims produced by combining multiple components.

Background: *Rhizobium* bacteria are naturally occurring bacteria that infect leguminous plants such as clover, alfalfa, beans and soy. Each species of bacteria will only infect certain types of plants, for example *R. meliloti* will only infect alfalfa and sweet clover, and *R. phaseoli* will only infect garden beans. It was assumed in the prior art that all *Rhizobium* species were mutually inhibitive, because prior art combinations of different bacterial species produced an inhibitory effect on each other when mixed together, with the result that their efficiency was reduced. Applicant has discovered that there are particular strains of each *Rhizobium* species that do not exert a mutually inhibitive effect on each other, and that these strains can be isolated and used in mixed cultures. Applicant has also discovered that certain *Rhizobium* species, when mixed together, exhibit biological properties that are different than in nature. For example, in nature or by itself, *R. californiana* will only infect lupine. When mixed with *R. phaseoli*, however, *R. californiana* will infect both lupine and wild indigo. *R. californiana* and *R. phaseoli* are not known to occur together in nature.

Claims:

1. An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium*, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.
2. An inoculant for leguminous plants comprising a mixture of *Rhizobium californiana* and *Rhizobium phaseoli*.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. Because both claims are directed to a statutory category, *e.g.*, a composition of matter (*Step 1: YES*), and are nature-based products (a mixture of bacteria), the markedly different characteristics analysis is used to determine if the nature-based products are exceptions.

Claim 1: Ineligible. There is no indication in the specification that the claimed mixture of bacteria has any characteristics (structural, functional, or otherwise) that are different from the naturally occurring

bacteria. Thus, the mixture does not have markedly different characteristics from what occurs in nature, and is a "product of nature" exception. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Because the claim does not include any additional features that could add significantly more to the exception (*Step 2B: NO*), the claim does not qualify as eligible subject matter, and should be rejected under 35 U.S.C. § 101.

The inoculant of claim 1 was held to be ineligible subject matter in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948):

> Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable. The aggregation of select strains of the several species into one product is an application of that newly-discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.

Recently, the Supreme Court looked back to this claim as an example of ineligible subject matter, stating that "the composition was not patent eligible because the patent holder did not alter the bacteria in any way." *Myriad*, 133 S. Ct. at 2117.

Claim 2: Eligible. In nature, *R. phaseoli* only infects garden beans, and *R. californiana* only infects lupine. When mixed together as claimed, the combination now infects a third species of plant: *R. californiana* infects both lupine and wild indigo, but *R. phaseoli* continues to only infect garden beans. The combination of species thus has changed *R. californiana* such that, when combined with *R. phaseoli*, it has a different characteristic (biological function) than it had in nature, *i.e.*, the claimed combination infects a new group of leguminous plants (wild indigo) as compared to the naturally occurring bacteria by themselves. This functional difference rises to the level of a marked difference, and accordingly the claimed mixture is not a "product of nature" exception. Note that unless the examiner can show that this particular mixture of bacteria exists in nature, this mere possibility does not bar the eligibility of this claim. *See, e.g., Myriad*, 133 S. Ct. at 2119 n.8 ("The possibility that an unusual and rare phenomenon *might* randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable" (emphasis in original)). Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

7. Nucleic Acids

This example illustrates that changes in genetic information/structure (claims 2 and 4), or physical structure (claim 3), as compared to a product's natural counterpart can demonstrate markedly different characteristics.

Background: Virginia nightshade is a naturally occurring plant that grows wild in the Shenandoah Valley of Virginia. When damaged, the leaves of Virginia nightshade produce a hormone called Protein W, which activates chemical defenses against herbivores. Protein W is naturally encoded by Gene W, which is part of chromosome 3 in Virginia nightshade and has the nucleic acid sequence disclosed as SEQ ID NO: 1. The specification also discloses substitution modifications of Gene W, *e.g.*, nucleic acids having one or more nucleotide bases that are substituted with different bases relative to SEQ ID NO: 1. For

example, one of the disclosed modifications changes a naturally occurring adenine to a guanine, *e.g.*, the first nine nucleotides are "TAC GGG AAA" in naturally occurring Gene L and "TAC GGG AAG" in the modified nucleic acid. Some of the modifications are silent, meaning that no change occurs in the encoded protein. It is known in the art that some silent modifications affect characteristics of nucleic acid such as transcription rate and splicing, and that some do not. No substitution modifications of Gene W are known to occur in nature. The modified nucleic acids have 90% or greater identity to SEQ ID NO: 1. The specification discloses labeling the nucleic acids, *e.g.*, with a fluorescent or radioactive label.

The specification discloses vectors comprising SEQ ID NO: 1 and a heterologous nucleic acid. The specification defines "heterologous" nucleic acid sequences as nucleic acid sequences that do not naturally occur in Virginia nightshade, *e.g.*, sequences from other plants, bacteria, viruses, or other organisms. Disclosed heterologous nucleic acids include plant viral vectors such as tobacco mosaic virus, and viral promoters such as the cauliflower mosaic virus (CaMV) 35S promoter. The viral promoters cause different expression of Gene W as compared to its natural expression levels in Virginia nightshade, *e.g.*, Gene W is expressed all the time (constitutively) as opposed to only in response to leaf damage.

Claims:

1. Isolated nucleic acid comprising SEQ ID NO: 1.
2. Isolated nucleic acid comprising a sequence that has at least 90% identity to SEQ ID NO: 1 and contains at least one substitution modification relative to SEQ ID NO: 1.
3. The isolated nucleic acid of claim 1, further comprising a fluorescent label attached to the nucleic acid.
4. A vector comprising the nucleic acid of claim 1 and a heterologous nucleic acid sequence.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. Because all of the claims are directed to a statutory category, *e.g.* a composition of matter (*Step 1: YES*), and are nature-based products (a nucleic acid), the markedly different characteristics analysis is used to determine if the nature-based products are exceptions.

Claim 1: Ineligible. The claimed nucleic acid has a different structural characteristic than naturally occurring Gene W, because the chemical bonds at each end were severed in order to isolate it from the chromosome on which it occurs in nature, but has the same nucleotide sequence as the natural gene. The claimed nucleic acid has no different functional characteristics, *i.e.*, it encodes the same protein as the natural gene. Under the holding of *Myriad*, this isolated but otherwise unchanged nucleic acid is not eligible because it is not different enough from what exists in nature to avoid improperly tying up the future use and study of naturally occurring Gene W. In other words, the claimed nucleic acid is different, but not markedly different, from its natural counterpart in its natural state (Gene W on chromosome 3), and thus is a "product of nature" exception. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Because the claim does not include any additional features that could add significantly more to the exception (*Step 2B: NO*), the claim does not qualify as eligible subject matter, and should be rejected under 35 U.S.C. § 101.

Claim 2: Eligible. The claim is limited to nucleic acids in which the nucleotide sequence has been changed to contain at least one non-naturally occurring substitution modification relative to SEQ ID NO: 1. All of the claimed nucleic acids have different structural characteristics than the naturally occurring nucleic acid, *e.g.*, one or more nucleotides have been changed relative to the natural sequence. Some of the claimed nucleic acids may have different functional characteristics, *e.g.*, they may encode a different protein than the natural gene. Because the structural differences between the claimed nucleic acids and their natural counterparts are enough to ensure that the claim is not improperly tying up the future use of naturally occurring Gene W, they rise to the level of a marked difference, and so the claimed nucleic acids

are not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 3: Eligible. The claim is limited to a molecule that includes a nucleic acid and a fluorescent label, which combination does not occur in nature as a single molecule. The claimed molecule thus has different structural characteristics than the naturally occurring nucleic acid and label (single molecule vs. two separate molecules). It also has different functional characteristics (the labeled nucleic acid is now fluorescent, whereas the natural gene is not). These differences rise to the level of a marked difference, and so the claimed molecule is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 4: Eligible. The claim is limited to vectors comprising a non-natural combination of Gene W (SEQ ID NO: 1) with a sequence from another organism, and thus does not read on the naturally occurring chromosome in Virginia nightshade. This non-natural combination results in the vectors having a different genetic structure and sequence than the naturally occurring nucleic acids, *i.e.*, different structural characteristics. Some of the claimed vectors may have different functional characteristics, depending on the selected heterologous sequence. These differences rise to the level of a marked difference, and so the claimed vector is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

8. Antibodies

This example illustrates that products created by human manipulation of natural processes (claims 2 and 3), as well as products that are changed in structure as compared to a product's natural counterpart (claims 4 and 5), can have markedly different characteristics.

Background: Newly discovered *Staphylococcus texana* bacteria have an antigen called Protein S on their outer surface. The specification describes the discovery of naturally occurring antibodies to Protein S in mice and wild coyotes living in Texas. No human antibodies to Protein S are naturally occurring. Antibodies have two types of domains: (1) constant domains such as the Fc domain, which are unvarying in antibodies of a particular class (*e.g.*, IgA) within a species; and (2) variable domains comprising complementarity determining regions (CDRs) that bind to an antigen and that vary from antibody to antibody.

The specification describes multiple types of antibodies to Protein S, including:

- murine antibodies, that were created by injecting laboratory mice with Protein S;
- human antibodies, that were created by injecting transgenic mice with Protein S;
- chimeric antibodies (defined as antibodies that have murine variable domains and human constant domains);
- humanized antibodies (defined as antibodies having murine CDRs but are otherwise human); and
- antibodies with variant Fc domains (defined as antibodies having an Fc domain that is engineered to comprise at least one amino acid modification relative to a wild-type Fc domain).

It is well-known in the art that murine antibodies have different constant domains than human and coyote antibodies, and that murine antibodies may cause allergic reactions and anaphylactic shock when administered to humans or coyotes. The specification discloses a particular murine antibody created by applicants, comprising SEQ ID NOs: 7-12 as its six CDR sequences. There is no naturally occurring antibody that has this particular combination of CDR sequences. It is well-known in the art that chimeric and humanized antibodies are less immunogenic to humans than murine antibodies. It is also well-known that antibodies with variant Fc domains may exhibit different characteristics (*e.g.*, increased cytotoxicity and/or serum half-life) than antibodies with wild-type Fc domains.

Claims:

1. An antibody to Protein S.

2. The antibody of claim 1, wherein the antibody is a human antibody.
3. The antibody of claim 1, wherein the antibody is a murine antibody comprising complementarity determining region (CDR) sequences set forth as SEQ ID NOs: 7-12.
4. The antibody of claim 1, wherein the antibody is a chimeric or humanized antibody.
5. The antibody of claim 1, wherein the antibody comprises a variant Fc domain.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. Because all of the claims are directed to a statutory category, *e.g.*, a composition of matter (*Step 1: YES*), and are nature-based products (an antibody), the markedly different characteristics analysis is used to determine if the nature-based products are exceptions.

Claim 1: Ineligible. As described in the specification, some antibodies to Protein S are naturally occurring in mice and wild coyotes living in Texas, while other antibodies to Protein S (such as chimeric antibodies) have non-natural forms and may contain domains from multiple species. The claim thus encompasses antibodies that are structurally identical to naturally occurring antibodies, and antibodies that are structurally changed. Because there is no difference in characteristics (structural, functional, or otherwise) between the claimed and naturally occurring antibodies for at least some of the embodiments encompassed by the claim, the claimed antibodies do not have markedly different characteristics, and thus are a "product of nature" exception. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Because the claim does not include any additional features that could add significantly more to the exception (*Step 2B: NO*), the claim does not qualify as eligible subject matter, and should be rejected under 35 U.S.C. § 101.

Claim 2: Eligible. The claim is limited to human antibodies to Protein S. No human antibodies to Protein S are naturally occurring. The claimed antibodies have different complementarity determining regions (CDRs) than what exists in nature, and therefore have different structural (*e.g.*, different amino acid sequences and three-dimensional structures) and functional (*e.g.*, bind to different antigens) characteristics. These differences rise to the level of a marked difference, and so the claimed antibodies are not "product of nature" exceptions. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 3: Eligible. The claim is limited to murine antibodies comprising complementarity determining region (CDR) sequences set forth as SEQ ID NOs: 7-12. Some murine antibodies to Protein S occur in nature, and it is possible that nature might randomly create a murine antibody having the CDR sequences of SEQ ID NOs: 7-12. But unless the examiner can show that this particular murine antibody exists in nature, this mere possibility does not bar the eligibility of this claim. *See, e.g., Myriad*, 133 S. Ct. at 2119 n.8 ("The possibility that an unusual and rare phenomenon *might* randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable" (emphasis in original)). Because the claimed antibodies have different CDRs than what exists in nature, they have different structural (*e.g.*, different amino acid sequences and three-dimensional structures) and functional (*e.g.*, bind to different antigens) characteristics. These differences rise to the level of a marked difference, and so the claimed antibodies are not "product of nature" exceptions. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 4: Eligible. The claim is limited to chimeric and humanized antibodies, which are defined as fusion proteins formed by physically fusing together part of a murine antibody (CDRs or variable domains) and part of a human antibody (constant domains). The claimed antibodies have different structural characteristics than natural antibodies, because the combination of murine and human antibody fragments into a single antibody molecule does not exist in nature. There may also be differences in functional characteristics, *e.g.*, chimeric antibodies are typically less immunogenic to humans than murine

antibodies. These differences rise to the level of a marked difference, and so the claimed antibodies are not "product of nature" exceptions. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 5: Eligible. The claim is limited to antibodies comprising a variant Fc domain, which is defined as an Fc domain that is engineered to comprise at least one amino acid modification relative to a wild-type Fc domain. The claimed antibodies have different structural characteristics (*e.g.*, different amino acid sequences and three-dimensional structures) than natural antibodies, and may also have different functional characteristics (*e.g.*, different cytotoxicity and/or serum half-life). These differences in characteristics rise to the level of a marked difference, and so the claimed antibodies are not "product of nature" exceptions. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

9. Cells

This example illustrates that a man-made product identical to a naturally occurring product does not have markedly different characteristics (claim 1), but that changes in phenotype caused by human manipulation can result in markedly different characteristics (claims 2 and 3). It also demonstrates the application of the "significantly more" analysis to claims directed to a "product of nature" exception (claims 4 and 5).

Background: Human stem cells are naturally occurring cells that can develop, through a process called differentiation, into many different types of cells, such as cardiac cells, skin cells, and so on. Stem cells have utility in regenerative medicine, which involves repairing diseased tissues or organs. One type of diseased tissue that often needs repair is the heart's pacemaker, which is formed from pacemaker cells that generate electrical impulses to control heart rate. In nature, pacemaker cells can be identified via a protein called marker P located on the cell surface. The pacemaker cells contain genes that are capable of expressing a protein called marker Z, but in nature these genes are never expressed (there are no naturally occurring pacemaker cells that have marker Z on their surface).

Applicant's specification discloses differentiating stem cells into pacemaker cells, for use in regenerating damaged heart tissue. Applicant discloses isolating stem cells from human volunteers, and then culturing those cells in a particular growth medium in the presence of growth factor A, at various temperatures. Isolation does not change the cells in any way, but applicant's culture conditions cause the stem cells to differentiate into pacemaker cells. Some of the man-made pacemaker cells produced by applicant are genetically and phenotypically identical (*e.g.*, express marker P) to naturally occurring pacemaker cells. Other man-made pacemaker cells produced by applicant are genetically identical, but have a different phenotype (*e.g.*, express marker Z and exhibit increased efficiency in utilizing oxygen) than naturally occurring pacemaker cells. Isolation of these man-made cells does not change them in any way.

The increased oxygen utilization efficiency of the pacemaker cells expressing marker Z is advantageous in the regeneration of heart tissue in patients who are recovering from damage to the heart, such as that caused by a myocardial infarction (heart attack). Applicant has discovered that a mixed population of pacemaker cells that is about 10-15% positive for marker Z (*i.e.*, about 10-15% of the cells in the population express marker Z), and about 85-90% positive for marker P (*i.e.*, about 85-90% of the cells in the population express marker P), can be injected into a patient's heart in order to regenerate a pacemaker *in vivo* (in a patient's body). This successful regeneration is possible because the cells interact with each other to affect their growth rates, *e.g.*, the cells expressing marker P grow faster in the mixed population than when they are by themselves. However, a cell population with fewer (or no) cells expressing marker Z is not capable of regenerating a pacemaker, because the cell population is starved of oxygen before it can become established in the patient.

The specification discloses compositions including populations of pacemaker cells in containers, such as flasks and petri dishes, which are routinely and conventionally used in laboratories to hold cells. Also

disclosed are compositions including populations of pacemaker cells in biocompatible three-dimensional scaffolds. The specification defines "biocompatible three-dimensional scaffolds" as being three-dimensional structures constructed of naturally occurring materials (such as polysaccharides or proteins) that are unchanged from their natural state, in which they are associated with non-cardiac cells, but that have been removed from their natural environment. The specification specifically excludes cardiac tissue from the definition of "biocompatible three-dimensional scaffolds". The specification also discloses that compositions including populations of pacemaker cells in the biocompatible three-dimensional scaffolds can be implanted directly into a patient, where they facilitate faster tissue regeneration than when pacemaker cells are implanted by themselves, because the scaffold provides mechanical support for the implanted cells to grow.

Claims:

1. An isolated man-made human pacemaker cell.
2. An isolated man-made human pacemaker cell expressing marker Z.
3. A population of human pacemaker cells, wherein the population is about 10-15% positive for marker Z, and 85-90% positive for marker P.
4. A composition comprising a population of isolated man-made human pacemaker cells in a container.
5. A composition comprising a population of isolated man-made human pacemaker cells in a biocompatible three-dimensional scaffold.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. All of the claims are directed to a statutory category, *e.g.*, a composition of matter (*Step 1: YES*).

Claim 1: Ineligible. Because the claim is a nature-based product, *i.e.*, a cell, the nature-based product is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. As described in the specification, some of the man-made cells are identical to what exists in nature (*e.g.*, same genotype and phenotype), while others are phenotypically different from what exists in nature (*e.g.*, express marker Z and have increased oxygen utilization), and these difference arose due to applicant's efforts. The claim thus encompasses cells that are identical (no difference in characteristics) to naturally occurring cells, and cells that are phenotypically different. Because there is no difference between the claimed and naturally occurring cells for at least some of the embodiments encompassed by the claim, the claimed cells do not have markedly different characteristics, and thus are a "product of nature" exception. *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1338-39 (Fed. Cir. 2014). Accordingly, the claim is directed to an exception (*Step 2A: YES*). Because the claim does not include any additional features that could add significantly more to the exception (*Step 2B: NO*), the claim does not qualify as eligible subject matter, and should be rejected under 35 U.S.C. § 101.

Claim 2: Eligible. The claim is limited to human pacemaker cells that express marker Z, which are nature-based products. No human pacemaker cells expressing marker Z are naturally occurring. As described in the specification, the claimed cells are exact genetic replicas of naturally occurring pacemaker cells, that were produced from naturally occurring stem cells. However, the claimed cells are phenotypically different than natural pacemaker cells, in that they express marker Z and have increased oxygen utilization efficiency. Further, these phenotypic differences were created by applicant's efforts (*e.g.*, by culturing the stem cells in a particular growth medium in the presence of growth factor A, at various temperatures), and were not the work of nature. These phenotypic differences rise to the level of a marked difference, and accordingly the claimed cell is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 3: Eligible. The claim is limited to a population of human pacemaker cells, where about 10-15% of the cells express marker Z, and about 85-90% express marker P. Because the claim is a nature-based

product, *i.e.*, a combination of cells, the nature-based product (the population) is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. As discussed above with respect to claims 1 and 2, the cells expressing marker Z have markedly different characteristics than naturally occurring cardiac pacemaker cells because of their phenotypic differences, but the cells expressing marker P do not have markedly different characteristics because they are identical to naturally occurring pacemaker cells. However, as described in the specification, when these cells are mixed together in the claimed ratio to form the claimed population, the cells interact with each other to affect their growth rates, *e.g.*, the cells expressing marker P grow faster in the mixed population than when they are by themselves. Naturally occurring pacemaker cells do not grow at this rate in their natural state. This difference in biological properties (rate of cell growth) between the claimed cell population and naturally occurring human pacemaker cells rises to the level of a marked difference, and accordingly the claimed population is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 4: Ineligible. Because the claim recites a nature-based product, *i.e.*, the population of cells, the nature-based product is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. As explained with respect to claim 1, isolated man-made pacemaker cells do not have markedly different characteristics due to their isolation or human manufacture. There is no indication in the specification that placing the cells in a generic container results in the cells having any characteristics (structural, functional, or otherwise) that are different from the naturally occurring cells in their natural state. Thus, the claimed population of cells does not have markedly different characteristics from what occurs in nature, and is a "product of nature" exception. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. Although the claim recites a container, use of a container to hold cells is not only well-understood, routine and conventional activity already engaged in by the scientific community, it is also required for growing and using the cells. Additionally, the claim recites the container at such a high level of generality that it merely tells a scientist to use whatever container she wishes to use. Therefore, the claim as a whole adds nothing significantly more to the "product of nature" itself. Thus, the claim does not amount to significantly more than the judicial exception itself (*Step 2B: NO*). The claim does not qualify as eligible subject matter, and should be rejected under 35 U.S.C. § 101.

Claim 5: Eligible. Because the claim is a nature-based product, *i.e.*, a combination of cells and a scaffold, the nature-based product (the combination) is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. As explained with respect to claim 1, isolated man-made pacemaker cells do not have markedly different characteristics due to their isolation or human manufacture. There is also no indication in the specification that placing the cells into a biocompatible three-dimensional scaffold results in the cells or the scaffold having any characteristics (structural, functional, or otherwise) that are different from the naturally occurring cells or scaffold in their natural state. Thus, the claimed population of cells, and the claimed scaffold, do not have markedly different characteristics from what occurs in nature, and are "product of nature" exceptions. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. The recitation of the biocompatible three-dimensional scaffold in combination with the pacemaker cells is not required for growing or using the cells, because the cells can be grown or used in other containers, and is not recited at a high level of generality. The addition of the pacemaker cells to the scaffold confines the claim to a particular useful application of the scaffold (repair of cardiac tissue), because the pacemaker cells are not routinely required for all practical uses of the scaffold. Further, the combination of these elements does more than generally link these two judicial exceptions together; as described in the specification, this combination improves the technology of regenerative medicine, by facilitating faster tissue regeneration than when pacemaker cells are implanted

by themselves. Thus, the claim amounts to significantly more than the judicial exception itself (*Step 2B: YES*), and qualifies as eligible subject matter.

10. Food

This example illustrates the difference between a nature-based product claim having multiple components that are unchanged because they are not combined (claim 1), and a nature-based product claim having multiple components that are changed by their combination (claim 2).

Background: Goats are naturally occurring animals that produce milk to feed their young. Humans have consumed goat milk and products made from goat milk (*e.g.*, cheese and yogurt) for centuries. One well-known method of making goat yogurt is to create a starter culture by mixing raw goat milk with bacteria, and then heating the starter culture to about 115 degrees Fahrenheit for several hours so that the bacteria can ferment the milk. The fermentation causes the conversion of lactose (milk sugar) in the goat milk into lactic acid, and this chemical change results in a physical change (the thickened consistency of the yogurt as compared to the goat milk). The lactic acid also makes the yogurt have a tangy flavor. Multiple species of bacteria are known as useful in making yogurt, including *Streptococcus thermophilus* (a naturally occurring bacterial species).

Applicant has discovered a new naturally occurring bacterial species that it named *Lactobacillus alexandrinus*. Goat milk yogurt made with *L. alexandrinus* has a pleasant tangy flavor. Neither *S. thermophilus* nor *L. alexandrinus* occur naturally in goat milk, and these bacteria do not occur together in nature. Applicant has also discovered that when mixed, *S. thermophilus* and *L. alexandrinus* have different properties than either bacteria has alone: (1) the mixed bacteria act synergistically to ferment goat milk at twice the speed than either bacteria can ferment by itself; and (2) the resultant goat yogurt is much lower in fat than either bacteria can produce when used by itself. Applicant discloses compositions comprising a goat milk starter comprising goat milk mixed with *S. thermophilus* and *L. alexandrinus*. Applicant also discloses kits for preparing goat milk yogurt. The kits comprise a separate packet of *S. thermophilus*, and a separate packet of *L. alexandrinus*, and may also comprise instructions for combining the two bacterial species with goat milk to make yogurt.

Claims:

1. A kit for preparing goat milk yogurt comprising: *Streptococcus thermophilus* and *Lactobacillus alexandrinus*.
2. A yogurt starter culture comprising: goat milk mixed with *Streptococcus thermophilus* and *Lactobacillus alexandrinus.*

Analysis of Claims:

These claims have been analyzed for eligibility in accordance with their broadest reasonable interpretation. Because both claims are directed to a statutory category, *e.g.*, a composition of matter (*Step 1: YES*), and are nature-based products (goat milk and/or bacteria), the markedly different characteristics analysis is used to determine if the nature-based products are exceptions.

Claim 1: Ineligible. As described in the specification, both *S. thermophilus* and *L. alexandrinus* are naturally occurring bacteria. There is no indication in the specification that the claimed bacteria have any characteristics (structural, functional, or otherwise) that are different from the naturally occurring bacteria. Because the bacterial species in the kit are not mixed, but instead are separate from each other, their inclusion in the same kit does not change their characteristics. Although the user of the kit may choose to mix the bacteria together at some time in the future, that mixture, which may or may not exist in the future is not a part of the claimed invention. *In re Venezia*, 530 F.2d 956, 958-59 (CCPA 1976). Thus, the bacterial species in the kit do not have markedly different characteristics from their natural counterparts in their natural state, and are "product of nature" exceptions. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Because the claim does not include any additional features that

could add significantly more to the exceptions (*Step 2B: NO*), the claim does not qualify as eligible subject matter, and should be rejected under 35 U.S.C. § 101.

Claim 2: Eligible. As described in the specification, when *S. thermophilus* and *L. alexandrinus* are mixed, the two bacterial species have different characteristics than either species does on its own, *e.g.*, they act together to ferment milk into a lower fat yogurt than either bacteria can produce when individually mixed with the milk. Thus, the mixture of the bacteria and milk has different functional characteristics (lower fat content) than the naturally occurring bacteria (or milk) by itself. These differences rise to the level of a marked difference, and accordingly the claimed starter culture is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.