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Patent Eligible Claims Post-*Alice*: Section 101 and the New USPTO Guidelines

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

National Environmental Policy Act

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

Paperwork Reduction Act

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

Regulatory Flexibility Act

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

significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

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

a. Does not have an annual effect on the economy of \$100 million.
b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

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

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

Unfunded Mandates

This rule will not impose an unfunded Mandate on State, local, or tribal governments or the private sector

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

List of Subjects in 30 CFR Part 934

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 1, 2014.

Ervin Barchenger,
Acting Director, Western Region.

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

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

PART 934—NORTH DAKOTA

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

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

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

§ 934.15 Approval of North Dakota regulatory program amendments.

* * * * *

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

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

§ 934.16 Required program amendments.

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

(a)–(cc) [Reserved]

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

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DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO–P–2014–0058]

2014 Interim Guidance on Patent Subject Matter Eligibility

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Examination guidance; request for comments.

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

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

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

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

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

SUPPLEMENTARY INFORMATION: Section 2106 of the Manual of Patent Examining Procedure (MPEP) sets forth guidance

for use by USPTO personnel in determining subject matter eligibility under 35 U.S.C. 101. See MPEP 2106 (9th ed. 2014). The USPTO has prepared this Interim Eligibility Guidance for use by USPTO personnel in determining subject matter eligibility under 35 U.S.C. 101 in view of recent decisions by the Supreme Court. The following Interim Eligibility Guidance on patent subject matter eligibility under 35 U.S.C. 101 supplements the June 25, 2014, Preliminary Examination Instructions in view of the Supreme Court Decision in *Alice Corporation Pty. Ltd. v. CLS Bank International, et al.*¹ (June 2014 Preliminary Instructions) and supersedes the March 4, 2014, Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products (March 2014 Procedure)² issued in view of the Supreme Court decisions in *Association for Molecular Pathology v. Myriad Genetics, Inc.*³ and *Mayo Collaborative Services v. Prometheus Laboratories Inc.*⁴ Implementation of examination guidance on eligibility will be an iterative process continuing with periodic supplements based on developments in patent subject matter eligibility jurisprudence⁵ and public feedback.

The USPTO is seeking written comments on this guidance, as well as additional suggestions for claim examples to use for examiner training. Further, the USPTO plans to hold a public forum in mid-January 2015 in

order to discuss the guidance and next steps and to receive additional oral input. When the date and location are finalized, notice of the forum will be provided on the Office’s Internet Web site (<http://www.uspto.gov>).

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

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

¹ *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. ___, 134 S. Ct. 2347 (2014).

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

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

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

⁵ The Court of Appeals for the Federal Circuit has a number of pending appeals that could result in further refinements to the eligibility guidance, including for example, *University of Utah Research Foundation v. Ambry Genetics Corp.* (In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation), No. 14-1361 (Fed. Cir. filed Mar. 18, 2014), and *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. 14-1139 (Fed. Cir. filed Dec. 4, 2013).

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