

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 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,

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. Amby 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.

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