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[3510-16-P]

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

Docket No.: PTO-P-2016-0003

May 2016 Subject Matter Eligibility Update

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Request for comments.

SUMMARY: The United States Patent and Trademark Office (USPTO) issued the July 2015 Update: Subject Matter Eligibility (July 2015 Update) to provide further guidance to examiners in determining subject matter eligibility under 35 U.S.C. 101. The USPTO announced the July 2015 Update in the Federal Register, and sought public comment on the July 2015 Update. The USPTO has since issued a memorandum to the Patent Examining Corps titled “Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant’s Response to a Subject Matter Eligibility Rejection” in response to those public comments, which is available to the public on the USPTO’s Internet Web site. The memorandum seeks to improve examiner correspondence with

regard to subject matter eligibility rejections. Further, additional life science examples to assist examiners in making eligibility determinations have been published and are available on the USPTO's Internet Web site. The USPTO is now seeking public comment on subject matter eligibility on an on-going basis.

DATES: The comment period is open-ended, and comments will be accepted on an ongoing basis.

ADDRESSES: Comments 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: Regarding the examiner memorandum, contact Matthew Sked, by telephone at 571-272-7627, or Carolyn Kosowski, by telephone at 571-272-7688, both at the Office of Patent Legal Administration. Regarding the life science examples, contact June Cohan, by telephone at 571-272-7744, Ali Salimi, by telephone at 571-272-0909, or Raul Tamayo, by telephone at 571-272-7728, all at the Office of Patent Legal Administration.

SUPPLEMENTARY INFORMATION: On July 30, 2015, the USPTO issued the July 2015 Update to provide further guidance on subject matter eligibility in view of public comments received in response to the 2014 Interim Guidance on Patent Subject Matter Eligibility. An announcement was published in the Federal Register seeking public comment on the July 2015 Update. See July 2015 Update on Subject Matter Eligibility, 80 FR 45429 (July 30, 2015).

In response, the USPTO received a total of thirty-seven submissions from the public, which have been carefully considered by the USPTO. The USPTO has issued a memorandum to the Patent Examining Corps titled “Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant’s Response to a Subject Matter Eligibility Rejection” to improve examiner correspondence regarding subject matter eligibility rejections. A copy of the memorandum is available on the USPTO’s Internet website, on the patent examination guidance and training materials web page (<http://www.uspto.gov/patent/laws-and-regulations/examination-policy/examination-guidance-and-training-materials>). In particular, the memorandum provides guidance to examiners on (1) formulating a subject matter eligibility rejection; and (2) evaluating a response to a subject matter eligibility rejection.

The USPTO’s guidance materials concerning the subject matter eligibility requirements of 35 U.S.C. 101, including the above-mentioned memorandum, do not constitute substantive rulemaking and do not have the force and effect of law. These guidance

materials set out examination policy on rejections with respect to the Office's interpretation of the subject matter eligibility requirements of 35 U.S.C. 101 in view of decisions by the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit (Federal Circuit). The guidance materials were developed as a matter of internal Office management and are 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 the USPTO's guidance materials is not, in itself, a proper basis for either an appeal or a petition.

Additionally, the USPTO has produced new life science examples. A copy of the examples is available on the USPTO's Internet website, again on the patent examination guidance and training materials web page (<http://www.uspto.gov/patent/laws-and-regulations/examination-policy/examination-guidance-and-training-materials>). The examples provide exemplary subject matter eligibility analysis under 35 U.S.C. 101 of hypothetical claims and claims drawn from case law. The examples are intended as a teaching tool to assist examiners and the public in understanding how the Office would apply the eligibility guidance in certain fact-specific situations.

The USPTO further solicited topics for study under the Topic Submission for Case Studies Pilot Program. See Request for Submission of Topics for USPTO Case Studies, 80 FR 79277 (Dec. 21, 2015). The case studies will include a review of consistency of the application of subject matter eligibility analyses under 35 U.S.C. 101 across the

examining corps to determine the quality of the work product and indicate where improvements can be made to further improve consistency.

The July 2015 Update included an Appendix 3 containing select eligibility decisions from the Supreme Court and the Federal Circuit. This chart of decisions assists examiners in identifying the types of subject matter courts have previously found to be ineligible. Appendix 3 will continue to be updated with Federal Circuit decisions having opinions (precedential or non-precedential). While non-precedential decisions are not binding precedent, the opinions provide guidance and persuasive reasoning as outlined in Fed. Cir. R. 32.1(d). Appendix 3 will also continue to be updated with Federal Circuit decisions without opinion (Fed. Cir. R. 36) on appeals originating from the Patent Trial and Appeal Board. Federal Circuit decisions affirming a district court decision without opinion (Fed. Cir. R. 36) will no longer be added to Appendix 3 because they provide little benefit to examiners or the public.

As discussed previously, the memorandum and life science examples are available to the public on the USPTO's Internet Web site. The USPTO is now seeking public comment. The comment period is open-ended, and comments will be accepted on an ongoing basis. When it is determined that the period will close, advance notification will be made on the public comment webpage. The USPTO is particularly interested in public comments addressing the progress the USPTO is making in the quality of correspondence regarding subject matter eligibility rejections.

Date: May 2, 2016

Michelle K. Lee

Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

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