



May 2016

Follow @Paul_Hastings



Patent Office Issues Updated Guidelines on Section 101 Subject Matter Eligibility Determinations

By [Charles J. Hawkins](#) & [Patrick J. Stafford](#)

On May 6, 2016, the United States Patent and Trademark Office (USPTO) issued updated guidance regarding the patent eligibility of subject matter under 35 U.S.C. § 101. The updated materials include a memorandum to the Patent Examining Corps designed to provide examination instructions relating to the subject matter eligibility of claims under Section 101 as well as updates to its database of examples. Given the recent activity directed towards applying the various Section 101 subject matter eligibility decisions from the Supreme Court, such as *Alice*, *Mayo*, and *Myriad*, this pronouncement supplements the 2014 Interim Guidance on Subject Matter Eligibility and the July 2015 Update on Subject Matter Eligibility to provide further guidance and examples for determining patent-eligible subject matter.

One addition in the latest update is a Memorandum providing instructions to patent examiners on how to formulate a subject matter eligibility rejection and evaluate an applicant's response. The Memorandum reiterates the two-step eligibility analysis set forth in the 2014 Interim Guidance and instructs examiners on how to apply that analysis in formulating a rejection. Specifically, the guidelines state the examiner should begin by first identifying whether a specific claim limitation qualifies as a judicial exception. The Memorandum states "[t]he rejection must identify the specific claim limitations and explain why those claim limitations **set forth** a judicial exception (*e.g.*, an abstract idea)." In determining whether a claim limitation is a judicial exception, the Memorandum directs the examiner to prior court decisions, but cautions against going beyond the court's previously identified concepts.

In regards to the second step, the Memorandum states that the examiner should identify any additional elements in the claim beyond the judicial exception and explain why "the additional elements taken **individually**, and also taken **as a combination**, do not result in the claim as a whole amounting to significantly more than the judicial exception." The Memorandum emphasizes that examiners should not conduct a prior art search to determine if the claimed subject matter was well-known in the art.



A second addition in the latest update is the inclusion of more case examples to aid in determining whether subject matter is patent-eligible, including some long-awaited examples relating to the life sciences fields. In particular, the updated examples highlight situations in which patent claims exploiting biomarkers and other natural products may be deemed to be patent eligible. These life science case examples will likely aid the USPTO in finding more life science claims patent eligible subject matter.

The Examination Guidance and Training Materials, including the updated May 2016 materials, continue to be a useful resource for practitioners dealing with Section 101 issues. In particular, the appendix with the summary of Court Decisions provides a consolidated archive of determinations made on subject matter eligibility by the Supreme Court and the Federal Circuit and the Examples can be used to assist in analyzing subject matter eligibility. In addition, the May 2016 materials provide an update to the Index of Eligibility Examples to reflect the addition of life sciences examples. The most recent materials also provide a summary of *Enfish, LLC v. Microsoft Corp.* and another recent case decided by the Federal Circuit relating to Section 101. As such, these Guidance and Training Materials set forth a well-defined analytical approach to determining subject matter eligibility.



If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings Washington D.C. lawyers:

Charles J. Hawkins
1.202.551.1955

charleshawkins@paulhastings.com

Patrick J. Stafford
1.202.551.1946

patrickstafford@paulhastings.com

Paul Hastings LLP

Stay Current is published solely for the interests of friends and clients of Paul Hastings LLP and should in no way be relied upon or construed as legal advice. The views expressed in this publication reflect those of the authors and not necessarily the views of Paul Hastings. For specific information on recent developments or particular factual situations, the opinion of legal counsel should be sought. These materials may be considered ATTORNEY ADVERTISING in some jurisdictions. Paul Hastings is a limited liability partnership. Copyright © 2016 Paul Hastings LLP.