USPTO Issues New Guidelines for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena and/or Natural Products

By Jianming Jimmy Hao, Ph.D.

In 2013 and 2012, the U.S. Supreme Court handed down two important decisions in Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad) and Mayo Collaborative Services v. Prometheus Laboratories, Inc. (Mayo) regarding patent eligibility. The U.S. Patent and Trademark Office (USPTO) subsequently issued a one-page memorandum in June 2013, providing guidance for dealing with patent applications related to DNAs and promised a more comprehensive guidance.


The New Guidelines provide a three-inquiry framework for determining patent subject matter eligibility. Under this framework, a patent examiner determines whether a claim as a whole satisfies the requirement of patent subject matter eligibility under 35 U.S.C. § 101 and whether to raise a rejection under this section by finding answers to three questions:

1. Is the claimed invention directed to one of the four statutory patent-eligible subject matter categories: process, machine, manufacture or composition of matter?
2. Does the claim recite or involve one or more judicial exceptions?¹
3. Does the claim as a whole recite something significantly different than the judicial exception(s)?

For determining whether a claim as a whole recites something significantly different, the New Guidelines ask examiners to conduct a 12-factor analysis. Anticipating that the “significantly different” inquiry will vary greatly depending on the types of inventions, the New Guidelines include analysis on 14 exemplary claims across eight different areas. These New Guidelines should provide patent examiners, inventors and patent practitioners with much needed guidance in the post-Myriad/Mayo era.

For more information about this Alert, please contact Jianming Jimmy Hao at 609.895.7065 or jhao@foxrothschild.com, or any member of Fox Rothschild’s Intellectual Property Department.

¹ Judicial exceptions include abstract ideas, laws of nature/natural principles, natural phenomena and natural products.