

OVERVIEW OF USPTO PATENT-ELIGIBILITY GUIDANCE

On December 16, 2014, the United States Patent and Trademark Office (USPTO) issued the much-anticipated “2014 Interim Guidance on Patent Subject Matter Eligibility,” superseding the previous USPTO Guidance of March 4, 2014.

This previous Guidance, released ostensibly in response to recent Supreme Court jurisprudence in this area (*Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S.Ct. 1289 (2012); *Association for Molecular Pathology et al. v. Myriad Genetics, Inc. et al.*, 569 U.S. ___ (2013)), set forth a unitary framework under which all claims reciting or implicating any “natural product” or “natural law” would be scrutinized for compliance with 35 U.S.C. § 101. Under this previous Guidance, products were eligible for patenting *only if their structure* was “markedly different” from what occurs in nature, notwithstanding any new beneficial functions or utilities exhibited by the claimed product. And as applied to compositions containing multiple naturally-occurring products, Examiners were instructed to first dissect the composition into its component parts, and then compare each part *individually* against what occurs naturally (rather than consider the composition as a whole). The previous Guidance also implied, by its Examples, that only exceedingly narrow process claims could pass muster under § 101, if a natural product or law was implicated.

Not surprisingly, the previous Guidance was poorly received, and was met with a deluge of criticism (including that it was inconsistent with underlying law). The new Guidance goes some way to addressing this criticism. Notably, and perhaps in response to comments that the Examples in the previous Guidance were inconsistent with underlying law, the new Guidance limits its Examples to actual, decided, cases. Additionally, for product claims, the new Guidance instructs that a structural difference is not the only way to demonstrate a “marked difference” vis-à-vis what occurs in nature; “markedly different characteristics can [now] be expressed as the product’s structure, function, and/or other properties.” But for claims that recite just a single component which also occurs in nature (such as an isolated or purified chemical compound or protein), it remains to be seen to what extent the USPTO will consider “function, and/or other properties” – given the new Guidance’s statement that “[t]o show a marked difference, a characteristic must be changed as compared to nature, and cannot be an inherent or innate characteristic of the naturally-occurring counterpart.” That is to say, will the USPTO consider a

recited use in a product claim (*e.g.*, “a vaccine composition ...”) as relevant to this “marked difference test?”

Compositions containing multiple naturally-occurring components (and/or containing components in addition to the naturally-occurring product(s)) are also examined more reasonably under the new Guidance; in contradistinction to the previous Guidance, compositions are now to be considered *as a whole*, rather than dissected into their component parts. Hence, advantageous properties or results flowing from combining multiple naturally-occurring products – while not relevant under the old Guidance – could be used to rebut a § 101 rejection under the new Guidance.

Additionally, the USPTO should be commended for now taking a common-sense approach to addressing inventions that, while implicating natural laws and/or natural products, are clearly not nature’s handiwork. In the new Guidance, a “streamlined eligibility analysis” gives Examiners discretion to forego a detailed § 101 analysis; Examiners will first view the claims “as a whole” to see whether they “seek to tie up any judicial exception such that others cannot practice it.” If the claims are found not to tie up any judicial exception, then a more searching § 101 analysis is unnecessary. Perhaps this new streamlined approach will address many of the criticisms of the multi-factor test set forth in the previous Guidance.

The new Guidance also embraces the Supreme Court’s recently revitalized “inventive concept” test for process claims, supplementing the USPTO’s preliminary examination Guidelines released June 25, 2014, following *Alice Corporation Pty. Ltd. v. CLS Bank International et al.*, Case No. 13-298 (Supr. Ct., June 19, 2014). Therefore, the new Guidance is relevant to all technologies, not only to those implicating naturally-occurring phenomena.