IP FLASH

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Transformative Subject Matter Patent-Eligibility in the US

PATENT ELIGIBILITY *The US Supreme Court's holdings in Mayo[1], Myriad[2], and Alice[3], recent decisions by the US Court of Appeals for the Federal Circuit, and non-binding USPTO examination guidelines have drastically altered expectations regarding patent-eligible subject matter under 35 U.S.C. § 101 and have introduced a need to strategically reassess both mature and developing patent portfolios.*

In Alice, the Supreme Court spelled out Mayo's determination of patent-eligibility as a two-part test: (1) "determine whether the claims are directed to a patent-ineligible concept" (i.e., judicial exceptions such as laws of nature, natural phenomena, or abstract ideas), and then (2) determine "whether the claim's elements, considered both individually and as an ordered combination, transform the nature of the claims into a patent-eligible application."[4]

So far, methods depending only on the natural process of drug metabolism (Mayo), naturally occurring DNA segments isolated from the genome (Myriad), cloned animals for which nothing in the claims or specification suggested a relevant difference as compared to naturally occurring donor animals (In Re Roslin Institute[5]), and DNA primers, even if synthetic, (University of Utah Research[6]) have all been held to be patent-ineligible subject matter by either the Supreme Court or Federal Circuit.

Based on the Supreme Court's holdings, the USPTO recently issued the 2014 Interim Guidance on Patent Subject Matter Eligibility ("Interim Guidance"[7]). While the Interim Guidance is not legally binding, the USPTO examiners use it as their guide for examination of patent applications.

The case law and Interim Guidance put a heavy burden on applicants to show subject matter patent-eligibility, yet significantly narrow the scope of allowable claims. Existing portfolios should be carefully reviewed to determine whether US claims meet patent-eligibility requirements and, if not, whether support exists for adding a limitation to avoid judicial exceptions in a pending, continuing, or, possibly, a reissue application. Care must be taken in drafting new patent applications to withstand § 101 scrutiny in the US, while not unnecessarily limiting the applications for prosecution outside the US, where subject matter eligibility standards are different[11]. ■

[1] 132 S. Ct. 1289 (2012). [2] 133 S. Ct. 2107 (2013). [3] 134 S. Ct. 2347 (2014). [4] Id. at 2350, 2355. [5] 750 F.3d 1333, 1339 (Fed. Cir. 2014). [6] Fed. Cir., No. 2014-1361, -1366, decided Dec. 17, 2014. [7] 79 Fed. Reg. 74618-33 (Dec. 16, 2014).

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