

Biotechnology Patenting in the Wake of the New U.S. Supreme Court Decision (*Alice v. CLS*)

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There has been considerable controversy in the United States in recent years about which types of inventions are eligible subject matter for patenting, and which do not meet the threshold because they are mere abstract ideas or laws of nature. This has been an especially hot issue for biotechnology patents, such as diagnostic methods and isolated genes, and computer-implemented patents for business methods.

Patent eligibility is determined according to a broadly written section of the U.S. patent statute, 35 U.S.C. §101, that some courts have been recently interpreting more narrowly. The U.S. Supreme Court released its highly anticipated decision in *Alice Corporation Pty. Ltd. v. CLS Bank International et al* on June 19, 2014. The unanimous U.S. Supreme Court, in two separate opinions, held that the computer-related claims are not patent-eligible under 35 U.S.C. §101 because they relate to an invention involving mitigating risk in financial settlements, which is merely an abstract idea. The Justice Thomas majority decision for the Court relied heavily on the reasoning of two of the Court's prior biotechnology decisions (*Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 12-398, and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 10-1150). The Court also followed its recent computer business method patent decision in *Bilski v. Kappos*, 561 U.S. 593. Sotomayor's short, concurring opinion further cited *Bilski*.

The Court followed the approach of the earlier decisions by stating that it "must first determine whether the claims at issue are directed to a patent-ineligible concept. If so, the Court then asks whether the claim's elements, considered both individually and 'as an ordered combination', 'transform the nature of the claim' into a patent-eligible application."

The method of computer implementation did not transform the abstract idea into a patent-eligible invention. The system and media claims were also patent-ineligible because they did not add anything further that made a difference.

Since the invention was a computer-implemented method, the case will have direct implications on biotechnology methods implemented by computer, e.g., biotechnology data mining, or methods of processing data to produce genetic or health information. There is no focus or comment in the Court's decision on patent eligibility of more conventional biotechnology inventions, such as diagnostic methods using chemical analysis or isolated genes, which were addressed in the Court's earlier decisions. It is clear that by citing its own earlier cases with approval, without further modification that could address concerns of biotechnology patent applicants, that the Court is committed to continuing to follow the same trail. This decision, therefore, does not provide news to improve the situation for the minority of biotechnology inventions that have issues with respect to patent eligibility because their subject matter is allegedly a law of nature or abstract idea. The bar for patentability of those biotechnology inventions remains raised. Patent applicants will have to be creative in drafting patent applications for these inventions, for example, by focusing on claims that include novel and inventive reagents in diagnostic methods. The USPTO has reviewed the Court decision and issued guidance to Examiners. Click [here](#) to view the USPTO's Preliminary Examination Instructions.