# CLIENT ALERT

## *CellZDirect*: Hope for Life Science Patents

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On July 5, 2016, the Federal Circuit upheld claims for a method of preserving hepatocytes by freezing them, thawing and re-freezing them as more than a patent-ineligible law of nature under 35 U.S.C. § 101. *Rapid Litigation Management Ltd., et al. v. CellzDirect, Inc., et al.*, No. 2015-1570 (Fed. Cir. Jul. 5, 2016) is the Federal Circuit's first attempt to clarify the restrictive interpretation of the requirements of Section 101 for a life sciences patent established in the seminal case *Mayo v. Prometheus*, 132 S.Ct. 1289 (2012) and its progeny. It is also the first time that the Federal Circuit has rejected a Section 101 attack on a patent involving a natural phenomenon since the Supreme Court's decision in *Alice Corp. Pty. Ltd. v. CLS Bank International et al*., 134 S.Ct. 2347 (2014). In *CellzDirect*, the Court held that the "[t]he end result of the [patent] claims is not simply an observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles…[r]ather, the claims are directed to a new and useful method of preserving hepatocyte cells."

In overturning the district court's grant of summary judgment of invalidity under 35 U.S.C. § 101, the Federal Circuit reasoned that a patent ***incorporating*** a law of nature is not automatically ineligible for patent protection. Instead, a court must determine what the concept of the invention is and what the claim is actually "directed to." In this case, the Court determined that the patent claims are directed to a "new and useful method of preserving" hepatocytes, not merely to the discovery that hepatocytes may survive a second freeze. Additionally, the Court stated that the claims of '929 patent "recite an improved process for preserving hepatocytes…it allows researchers to pool samples together in advance and preserve them for later use, rather than needing to wait until enough single samples are accumulated that can be pooled and used immediately." Therefore, the Court held that the claimed process is eligible for patent protection because it applies the discovery that hepatocytes can be frozen twice to achieve a new and useful preservation process.

This decision may help clarify the standard for patent eligibility under *Mayo* as applied to life sciences patents. In prior holdings, the Federal Circuit has held claims were directed to "a patent-ineligible concept when they amounted to nothing more than observing or identifying the ineligible concept itself." *Cellzdirect*, at 9. In so doing, the Court distinguished its prior case law. Previously, in *In re BRCA*, claims directed to methods for screening human germline for an altered BRCA1 gene by comparing the target DNA sequence with wildtype sequence were held to be patent-ineligible because comparing the two sequences was nothing more than an abstract mental process. *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig*., 774 F.3d 755, 761-63 (Fed. Cir. 2014). The Federal Circuit then reached the same conclusion about claims directed to methods for detecting paternally inherited cffDNA in the blood or serum of a pregnant female. *Ariosa Diagnostics, Inc. v. Sequenom, Inc*., 788 F.3d 1371, 1373-74 (Fed. Cir. 2015), *cert. denied*, No. 15-1102, 2016 WL 1117246 (June 27, 2016). Most recently, the Court held that claims to methods for detecting a coding region of DNA based on its relationship to noncoding regions were directed to patent-ineligible subject matter under 35 U.S.C. § 101 because the claims merely identified "information about a patient's natural genetic makeup." *Genetic Techs., Ltd. v. Merial L.L.C.*, 818 F.3d at 1369, 1373-75 (Fed. Cir. 2016). Although the claims in each of these cases employed method steps, the end result of the process, the essence of the whole, was a patent-ineligible concept.

*CellzDirect* serves as an important reminder that patent claims should be analyzed as a whole to determine patent eligibility under Section 101, and that patent claims directed in part to a law of nature are not necessarily patent ineligible. This holding should guide those drafting claims to include as many process or method details as possible, at least in some of the claims, even if the broader subject of the invention could be viewed as a patent-ineligible subject matter.

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