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Method for New and Useful Laboratory Technique Involving Law of Nature is Patent-Eligible

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In vacating a District Court grant of summary judgment that a patent directed to a cryopreservation process was invalid under 35 U.S.C. § 101 for being directed to a patent-ineligible law of nature, the Federal Circuit held that the claims were patent eligible and directed to a new and useful method of preserving hepatocyte cells. *Rapid Litigation Management v. Cellzdirect, Inc.*, 2015-1570 (Fed. Cir., July 5, 2016) (Chief Judge Prost authoring the opinion).

The Supreme Court has long held that laws of nature, natural phenomena, and abstract ideas are not patentable. The Supreme Court in *Alice Corp. v. CLS Bank Int'l* reiterated a two-part test for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, a court must determine whether the claims are directed to one of the patent-ineligible concepts. If so, the court will then consider the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application.

The patent at issue relates to a process of preserving hepatocytes. Prior methods of preserving hepatocytes involved cryopreservation where cells were frozen and then later thawed with viable cells then being recovered for testing, diagnostic, or treatment purposes. The prevailing wisdom was that hepatocytes could be frozen and thawed only once and then had to be used or discarded. The inventors discovered that some hepatocyte cells were capable of surviving multiple freeze-thaw cycles and that twice frozen cells behaved like cells that were once frozen. The improved process claimed in the patent at issue includes: separating previously frozen and thawed cells; recovering the viable cells; and refreezing the viable cells, wherein greater than 70% of the refrozen cells are viable after the second thaw.

In determining whether the claimed process was patent eligible, the Federal Circuit applied the Supreme Court's *Alice* two-part test. In step one, the Federal Circuit considered whether the claims were "directed to" a patent-ineligible concept. The Federal Circuit determined that the steps performed and the end result of a preparation of multi-cryopreserved cells that could be thawed for immediate use retaining 70% viability was more than merely being "directed to" the ability of cells to survive multiple freeze-thaw cycles. The Federal Circuit acknowledged that the inventors did discover this ability, but that the inventors didn't stop there, and that was not what they patented. Rather, "as the first party with knowledge of" the cells' ability, they were 'in an excellent position to claim *applications* of that knowledge.'" (quoting *Myriad*, 133 S. Ct. at 2120)(emphasis added).

The Court stated that "the end result of the patented process was not simply an observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles." Instead, the Federal Circuit found the claims satisfied section 101 because they were directed to a new and useful *laboratory*

technique. Citing the Supreme Court's decision in *Alice*, the Federal Circuit noted that this type of constructive process carried out by a skilled artisan to achieve a "new and useful end" is precisely the type of claim that is eligible for patenting. In the patent at issue, the end result was a new and useful *method of preserving the cells*. The fact that describing the process inherently includes a description of the hepatocytes ability to undergo the process does not make the method claim directed to that natural ability.

The Federal Circuit further stated that, when performing step one of the *Alice test*, it is not enough to merely identify a patent-ineligible concept underlying the claim; a court must determine whether the claim is "directed to" the patent-ineligible concept. While technically not needing to address the second *Alice* step, the Federal Circuit considered the second step and found that that even if the claims were directed to a patent-ineligible concept, the claims would still be patent-eligible because the claimed method of preservation improved upon an existing technological process and was sufficient to transform the process into an inventive application of a patent ineligible concept.

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