

PATENT-ELIGIBLE SUBJECT MATTTER LAW OF NATURE (PRECEDENTIAL)

RAPID LITIGATION MANAGEMENT LTD. v. CELLZDIRECT, INC., Appeal No. 2015-1570 (Fed. Cir. July 5, 2016). Before <u>Prost</u>, Moore and Stoll. Appealed from N.D. Ill. (Judge Shadur).

Background:

Plaintiff owns a patent directed to methods of producing a desired preparation of multi-cryopreserved hepatocytes. Plaintiff sued Defendants alleging that their process infringes the claims of Plaintiff's patent. In response, Defendant filed a motion for summary judgment of invalidity under §\$101 and 112. The district court granted the motion, finding the asserted claims invalid under §101 and dismissing the action with prejudice (without reaching the §112 issues).

In finding the patent invalid under §101, the district court applied the Supreme Court's two-step framework for determining patent eligibility. At step one, the district court concluded that the asserted claims are directed to an ineligible law of nature—the discovery that hepatocytes are capable of surviving multiple freeze-thaw cycles. At step two, the district court determined that the claimed process lacks the requisite inventive concept—upon discovering the cells' capability of surviving multiple freeze-thaw cycles, the inventors simply reapplied a well-understood freezing process.

Issue/Holding:

Did the district court err in holding that the asserted claims are not patent-eligible under §101? Yes, vacated and remanded.

Discussion:

The Federal Circuit determined that the claims at issue recite processes (i.e., new and useful methods of preserving hepatocyte cells) to achieve a desired outcome (e.g., methods of producing a thing—a desired preparation of multi-cryopreserved hepatocytes), not simply an observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles. Thus, the Federal Circuit determined that the claims at issue were distinguishable from the claims found unpatentable in *Myriad* and *Ariosa*. Regarding step one of the Supreme Court's two-step framework, the Federal Circuit explained it is not enough to merely identify a patent-ineligible concept underlying the claim. Instead, a determination must be made whether that patent-ineligible concept is what the claim is "directed to." Here, the Federal Circuit found that the claimed new and improved technique, for producing a tangible and useful result, fell squarely outside those categories of inventions that are "directed to" patent ineligible concepts.

The Federal Circuit also determined that even if Defendant was correct that the claims at issue were "directed to" hepatocytes' natural ability to survive multiple freeze-thaw cycles, the Federal Circuit would have found the claims at issue patent-eligible (under step two of the Supreme Court's two-step framework) because the additional elements of the claims were sufficient to transform the process into an inventive application of the patent ineligible concept (i.e., the claimed method was patent eligible because it applies the discovery that hepatocytes can be twice frozen to achieve a new and useful preservation process).

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