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Federal Circuit Reverses District Court on Patent Eligibility, Finding a Biological Method Patent Eligible

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On July 5, 2015, the Federal Circuit released a decision in *Rapid Litigation Management Ltd., formerly Celsis Holdings, Inc. v. Cellzdirect, Inc., No. 2015-1570 (Fed. Cir. July 5, 2016). The case continues the Federal Circuit's recent trend of decisions in favor of patent eligibility. On May 12, 2016, the Federal Circuit confirmed* that not all computer-implemented patents are directed to an abstract idea under step one of the *Alice* test in *Enfish, LLC v. Microsoft Corp.*, No. 2015-1244, 2016 U.S. App. LEXIS 8699 (Fed. Cir. May 12, 2016) (for more information, see our alert on *Enfish* **here**). A month and a half later, the Federal Circuit found that computer-implemented claims could involve an inventive step under step of the *Alice* test. *See* *Bascom Global Internet Servs., Inc. v. AT&T Mobility LLC*, No. 2015-1763 (Fed. Cir. June 27, 2016) (for more information, see our alert on *Bascom* **here**). *Cellzdirect* continues the trend by finding a biological method eligible for patent protection.

District Court

The invention at issue is a method for obtaining a preparation of hepatocytes, (a type of liver cell) capable of being repeatedly frozen and thawed. *Cellzdirect*, slip op. at 4. In the previous summary judgment decision, the district court had found the claims directed to a patent-ineligible law of nature—that hepatocytes are capable of surviving multiple freeze-thaw cycles—and that there was no inventive concept at step two of the *Alice* test because the process applied a well-understood freezing process. *Id.* at 1.

Federal Circuit

In overturning that decision, the Federal Circuit first summarized how the claimed process is an unexpected improvement over the prior art. *Id.* at 9. It then explained the Supreme Court's two-part test for distinguishing between patent ineligible and patent eligible subject matter. With regard to step one, which asks if the claim is directed to a patent ineligible concept such as a natural law, the Federal Circuit stated that the claims were not directed to the alleged "natural law" of "the cells' capability of surviving multiple freeze-thaw cycles" but to an "application" of that principle: "a new and useful laboratory technique for preserving hepatocytes." *Id.* at 8.The Court helpfully explained that "[t]his type of

constructive process, carried out by an artisan to achieve 'a new and useful end,' is precisely the type of claim that is eligible for patenting." *Id.*

The Federal Circuit explained that these claims were distinguishable over *Mayo* and *Alice*, and the other 101 cases it has recently decided with regard to laws of nature, because the claims did not claim the abstract idea but instead claimed "a new and useful method of preserving hepatocyte cells." *Id.* at 10. It found it notable that "the claims recite a '*method of producing* a desired preparation of multi-cryopreserved hepatocytes'" because it is similar to other patent-eligible claims covering "methods of producing things, or methods of treating disease." *Id.* The Federal Circuit explained that, just because a process can be described by "[d]escrib[ing] the natural ability of the subject matter to *undergo* the process[, that] does not make the claim 'directed to' that natural ability." *Id*. It gave analogous examples, such as a method of "treating cancer with chemotherapy" as not being directed to the natural law of "the cancer cells' inability to survive chemotherapy." *Id.*

Even though it already determined that the claims were not "directed to" a natural law at step one, the Federal Circuit proceeded to step two of *Alice* for good measure. It held that the claims contained an "inventive concept" because they improved an existing technological process, explaining that "[t]he claimed method is patent eligible because it applies the discovery that hepatocytes can be twice frozen to achieve a new and useful preservation process." *Id.*at 14. "That each of the claims' individual steps . . . were known independently in the art does not make the claim unpatentable" because step two looks at the claim elements individually and as a whole. *Id*. The Federal Circuit even discussed the prior art taught away from the combination of steps claimed, and explained that "[r]epeating a step that the art taught should be performed only once can hardly be considered routine or conventional. This is true even though it was the inventor's discovery of something natural that led them to do so." *Id.* at 15.

The Federal Circuit concluded by noting that: (1) the ease of execution of applying a natural law once it is discovered is irrelevant to a 101 analysis (although it may be relevant to a section 103 analysis for obviousness); and (2) while pre-emption is not the test for determining patent-eligibility, it is relevant in that it can provide additional support to the ultimate conclusion. *Id.* at 16.

Practical Impact

This decision continues the Federal Circuit's trend of finding claims patent-eligible under *Alice*, even in areas that often have eligibility problems, such as computer technology and biological processes.

We will continue to monitor developments in this area and report on them. In the meantime, if you have questions, please feel free to contact one of our attorneys.

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