The Federal Circuit Reins in the Law of Nature Doctrine

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A few months ago, the Court of Appeals for the Federal Circuit (CAFC) in *Rapid Litigation Management Ltd. v. CellzDirect, Inc.,* No. 15-1570 (Fed. Cir. July 5, 2016) overturned a lower court's finding of invalidity under the law of nature doctrine of 35 U.S.C. § 101 for a patented process involving re-freezing hepatocytes. The question before the court was whether the claims of U.S. Patent No. 7,604,929 (the "'929 patent") recited patent eligible subject under 35 U.S.C. § 101 when analyzed using the two-part test articulated in *Alice Corp. v. CLS Bank Int'l.* The CAFC held that the patented process was not "directed to a patent-ineligible law of nature," but rather a "new and improved way of preserving hepatocyte cells for later use." *Id.* at 2 and 9.

Hepatocytes are liver cells that are useful for testing, diagnostics, and treatment, and the relevant technical problem solved by the patent in this case was that the creation of pooled hepatocyte products could only be performed after one freezing cycle. As the court explained, the "[p]revailing wisdom . . .taught that cells could be frozen only once and then had to be used or discarded." The inventors of the '929 patent determined that one could re-freeze the hepatocytes and still have viable cells, and naturally claimed a method "compris[ing]: (A) subjecting previously frozen and thawed cells to density gradient fractionation to separate viable cells from non-viable ones; (B) recovering the viable cells; and (C) refreezing the viable cells."

Under step one of the two-part Alice test, the court examined whether this method claim was distinguishable from prior cases involving natural laws and natural relationships in order to determine whether the claim was "directed to one of [the] patent ineligible concepts," such cases including: *Genetic Technologies v. Merial L.L.C.,* 818 F.3d, 1369 (Fed. Cir. 2016), *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, No. 15-1102, 2016 WL 1117246 (June 27, 2016), and *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, (Fed. Cir. 2014). In Genetic Technologies, the CAFC held that the methods for detecting a coding region of DNA based on the coding region's relationship to non-coding regions amounted to no more than "identifying information about a patient's natural genetic makeup," while in *Ariosa*, the court opined that methods for detecting paternally inherited cffDNA in the blood or serum of a pregnant female exploited the natural phenomenon of the very existence and location of cffDNA being available in the pregnant female, and noted that the claim language in *Ariosa* did no more than identify the presence of the cffDNA itself. Finally, the claims in *In re BRCA* involved comparing two sequences of DNA, one target DNA sequence and one wild-type sequence, to detect alterations; the CAFC held that those claims were directed to a patent-ineligible "abstract mental process" of comparison of the two sequences. According to the court, the common denominator for these cases was that the claims at issue were "directed to" a patent-ineligible concept "when they amounted to nothing more than observing or identifying the ineligible concept itself." *Rapid Lit.,* Appeal No. 15-1570 at 9.

In contrast, the CAFC remarked that the claims involving refreezing the hepatocytes did not merely rely on "observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles." *Id.* at 10. Rather, the court reasoned that the patented invention "achieve[d] a better way of preserving the hepatocytes," and was therefore "directed to a new and useful method of preserving

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hepatocyte cells." *Id.* The court explained that claiming a process by "describ[ing] the natural ability of the subject matter to *undergo* the process does not make the claim 'directed to' that natural ability," and observed that claims directed to a method of "producing a new compound" could be found ineligible due to "the individual components' ability to combine to form the new compound." *Id.* Consequently, the CAFC determined that the claims of the '929 patent, directed to a "new and improved" "method of producing a desired preparation of multi-cryopreserved hepatocytes" were not directed to a patent ineligible concept. *Rapid Lit.*, Appeal No. 15-1570 at 13 (quoting '929 patent col. 19 l. 66-col. 20 l. 20).

The court's reasoning for step one of the Alice test relied on three main points. First, the claims recited a single method, of potentially many others, to produce a desired result. Second, the claim's final step involved "refreezing," as opposed to "observing," "identifying" or "comparing" (which were the final steps in those cases where the claims were found to be directed to a natural law). Third, the produced result of the method claim was an "improvement" over conventional preparation methods.

The result in *Rapid Litigation* does not appear to help distinguish *Ariosa*, where tests on cffDNA in the maternal bloodstream improved upon previous tests of fetal DNA by "avoid[ing] the risks of widely-used techniques that took samples from the fetus or placenta." However, the key conceptual difference between the claims in *Rapid Litigation* and *Ariosa* is that cffDNA had been present already in nature; all man had to do was extract the cffDNA from the blood or serum of a pregnant female and inspect it to gain the benefit of the information it contained. The cffDNA did not need to go through any additional treatment such as refreezing in order to be identified. Thus, it was insufficient in *Ariosa* that the resulting process was an improvement because the more easily accessible information was already readily available. Extrapolating this principle more broadly, a discovery that *applying step X will result in Y* may result in a patentable process because it is not directed to a natural law, while a discovery that *looking in a certain place and doing something there to find out something else* may not result in a patentable process because it may be directed to a natural law. In addition, it may be that *step X* must be included as part of a novel combination of steps that has not previously been performed in order for the process to be patent eligible. *See Rapid Lit.*, Appeal No. 15-1570 at 9.

While the court's determination in *Rapid Litigation* that the claim was not directed to a patent ineligible concept was dispositive, the court proceeded to the second step of the *Alice* test for completeness to determine whether additional elements apart from the patent ineligible concept, considered both individually and as an ordered combination, were significantly more than the ineligible concept itself. The CAFC held that "[e]ven if. . .the '929 patent [was] 'directed to' hepatocytes' natural ability to survive multiple freeze-thaw cycles" the claims would be patent-eligible under step two as well. *Rapid Lit.*, Appeal No. 15-1570 at 13. The court stated that a claim that is "directed to" a patent-ineligible concept, while also improving an existing technology process, is sufficient to transform the claim into an inventive application of the patent-ineligible concept. Addressing the claims at issue, the court observed that "[t]he benefits of the improved process over the prior art methods [were] significant . . . allow[ing] 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." *Rapid Lit.*, Appeal No. 15-1570 at 13.

The court noted that the fact that each of the individual steps in a claim were previously known does not defeat patentability of a claim, because previously known steps in combination may result in a patentable process. *Id.* However, it is insufficient to merely "add[] knowledge of the natural law" or "perform[] the same steps on a newly discovered, naturally occurring" composition of matter in order to make a claim patent eligible. *Id.* at 14. The claimed process of preserving hepatocytes by

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repeating the previously practiced steps was not only an improvement, but the combination was also "far from routine and conventional." *Id.* at 15. Consequently, it is "sufficient" at step two for a claim to contain significantly more than the ineligible concept itself when the claim is a new combination of steps that results in an improvement over the art. *See Rapid Lit.,* Appeal No. 15-1570 at 13-14.

The CAFC, in holding that the patent claims involving re-freezing hepatocytes recited patentable subject matter, reversed the lower court's finding of invalidity under 35 U.S.C. § 101. The court found that the claims recited an improved method of preserving hepatocytes as a new combination of steps featuring a final refreezing step rather than merely incorporating a final step of observing, identifying, or comparing some newly discovered, naturally occurring matter, and recited significantly more than hepatocytes' natural ability to survive multiple freeze-thaw cycles because the method was not merely routine and conventional and resulted in an improvement over the prior art. This decision gives patent drafters or prosecutors another basis to argue subject matter eligibility when the limitations of the claim form a new combination that solves a technological problem and when the result of practicing the method is an improvement to that technology.

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