Federal Circuit Offers Path Through Section 101 Thicket for Biotech Method Patents

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In its July 5, 2016 decision in *Rapid Litigation Management Ltd and In Vitro, Inc. v. CellzDirect, Inc. and Invitrogen Corp.*, the Federal Circuit held that patent claims directed to an improved method of cryopreserving certain liver cells constitutes patent-eligible subject matter under 35 U.S.C. § 101. The district court had granted summary judgment of invalidity, holding that the claims were directed to a law of nature: namely, that hepatocytes can survive multiple freeze-thaw cycles. Chief Judge Proust, joined by Judges Moore and Stoll, reversed the district court and, in doing so, shed some light on the Supreme Court's two-step subject-matter eligibility test as applied to inventions in the life sciences field.

The test articulated by the Supreme Court in the *Alice* and *Mayo* cases requires a court to determine (1) whether the claims at issue are directed to one of the judicial exceptions, such as a law of nature and (2) whether the additional claim limitations beyond the ineligible subject matter are sufficient to transform the process into an inventive application of otherwise ineligible subject matter. The lower courts have struggled in their application of this test, including what it means for a claim to be "directed to" a law of nature or natural phenomenon.

The *CellzDirect* decision offers meaningful guidance as to the proper application of the *Alice/Mayo* test. As to the first step, the Federal Circuit held that the district court erred in concluding that the claims are "directed to" a law of nature, finding instead that the claims "are directed to a new and useful laboratory technique for preserving hepatocytes." The Court emphasized that the inventors "employed their natural discovery [that these cells can survive multiple freeze-thaw cycles] to create a new and improved way of preserving hepatocytes for later use."

Importantly, the decision underscored the distinction between claims "directed to" and claims "involving" a law of nature. The Court commented that failing to draw this distinction would lead, incorrectly, to findings that a variety of patentable methods were "directed to" patent ineligible subject matter—e.g., methods of "producing a new compound (as directed to the individual components' ability to combine to form a new compound), treating cancer with chemotherapy (as directed to cancer cells' inability to survive chemotherapy), or treating headaches with aspirin (as directed to the human body's natural response to aspirin)". The Court's endorsement of claims such as these will come as good news to life sciences innovators. Where, as here, the claimed invention can be characterized as merely "involving" a natural law or phenomenon, it will satisfy section 101, and further inquiry under the *Alice/Mayo* test will be unnecessary.

In dicta, the Court also performed the second step of the test, providing further guidance on its application. The district court had reasoned that because each individual recited step of the claim was known independently in the art, the claim recited nothing more than "well understood, routine, conventional activity already engaged in by the scientific community." The Federal Circuit found this analysis to be erroneous, because it improperly considered each step alone rather than looking at the claim as a whole. The Court explained that, "[t]he individual steps of freezing and thawing were well known, but a process of preserving hepatocytes by repeating those steps was itself far from routine." On this basis, the Court concluded that even if the claims had been "directed to" patent ineligible subject matter in step one of the *Alice/Mayo* test, the claims still would be patentable because the steps, as a whole, "'transform[] the process into an inventive application' of the patent-ineligible concept." The decision stresses that "patent-eligibility does not turn on ease of execution or obviousness of the application [of the natural law or phenomenon]." Instead, those questions are examined under other provisions of the Patent Act, including 35 U.S.C. § 103.

This decision is welcome guidance for many in the life sciences industry who were disappointed by the Supreme Court's recent denial of certiorari in the high-profile *Ariosa v. Sequenom* case, where the Federal Circuit found Ariosa's diagnostic claims ineligible. One lesson from *CellzDirect* decision is that patent attorneys should strive to craft claims that "pass" step one of the *Alice/Mayo* test. To do so, they should

draft method claims to recite the specific, concrete steps performed in the method and should avoid reciting judicial exceptions where possible. For example, if a diagnostic claim can be presented as a series of concrete steps performed by a scientist for detecting an analyte, the claim should not include an unnecessary "wherein" clause reciting a correlation between the analyte and a disease state. Indeed, in Example 29 of its May 2016 Life Sciences Subject Matter Eligibility Examples, the USPTO appears to have anticipated the more rigorous step one analysis adopted by the Federal Circuit in this case.

And if a claim nevertheless is determined to be "directed to" ineligible subject matter such that patentability will depend on *Alice/Mayo*'s step two, the *CellzDirect* decision is an important tool to buttress an argument that the specific, ordered combination of steps recited in the claim as a whole are new, unconventional, and, therefore, patent-eligible, even if the individual steps in isolation might be known. Similarly, the *CellzDirect* decision can be used to push back on an examiner who blurs step two of the *Alice/Mayo* test with an obviousness analysis.

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