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MEMORANDUM

DATE: July 14, 2016

TO: Patent Examining Corps

FROM: Robert W. Bahr
Deputy Commissioner
for Patent Examination Policy

SUBJECT: Recent Subject Matter Eligibility Rulings (*Rapid Litigation Management v. CellzDirect* and *Sequenom v. Ariosa*)

The U.S. Supreme Court (Supreme Court) and U.S. Court of Appeals for the Federal Circuit (Federal Circuit) have recently issued rulings in subject matter eligibility cases concerning life sciences method claims: *Rapid Litigation Management v. CellzDirect* and *Sequenom v. Ariosa*. These cases do not change the subject matter eligibility framework, and the USPTO's current subject matter eligibility guidance and training examples are consistent with these cases. The decision in *Rapid Litigation Management* does, however, provide additional information and clarification on the inquiry for determining whether claims are directed to a judicial exception (Step 2A of the subject matter eligibility examination guidelines).

Rapid Litigation Management v. CellzDirect: On July 5, 2016, the Federal Circuit in *Rapid Litigation Management* held the claimed methods of cryopreserving hepatocyte cells **patent eligible** under 35 U.S.C. § 101 because they are not directed to a judicial exception. The claims recite a method of producing a preparation of hepatocytes "capable of being frozen and thawed at least two times," comprising performing density gradient fractionation to separate viable and non-viable hepatocytes, recovering the viable hepatocytes, and cryopreserving the recovered viable hepatocytes. The Federal Circuit determined that although the "inventors certainly discovered the cells' ability to survive multiple freeze-thaw cycles . . . that is not where they stopped, nor is it what they patented." Instead, the inventors "employed their natural discovery to create a new and improved way of preserving hepatocyte cells for later use." As a result, the court held the claims eligible under the first step of the *Mayo/Alice* framework (Step 2A in the USPTO's subject matter eligibility guidance).

In reaching its conclusion, the Federal Circuit highlighted several important points regarding the subject matter eligibility analysis, in particular regarding whether a claim is directed to law of nature (Step 2A). First, the court emphasized that the "directed to" analysis of a process claim requires more than "merely identify[ing] a patent-ineligible concept underlying the claim" and instead requires an analysis of whether "the end result of the process, the essence of the whole,

was a patent-ineligible concept." The end result of the claims at issue is not simply an observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles, but instead the claims recite a number of process steps (*e.g.*, fractionating, recovering, and cryopreserving) that manipulate the hepatocytes in accordance with their ability to survive multiple freeze-thaw cycles to achieve a desired outcome (a preparation of multi-cryopreserved viable hepatocytes). Because these claims were focused on a process for achieving this desired outcome, the court determined that they, like thousands of other claims that recite methods of producing things or methods of treating disease, were not directed to a judicial exception. This need to analyze the focus of the claims in Step 2A was also emphasized in the Federal Circuit's *Enfish* decision (discussed in the May 19, 2016 memorandum to examiners). Second, the court noted that these claims that apply a law of nature are distinguishable from the claims in *Mayo* and *Sequenom* that were found to be directed to a patent-ineligible concept when they "amounted to nothing more than observing or identifying the ineligible concept itself." The USPTO's current subject matter eligibility guidance (set out in the 2014 Interim Eligibility Guidance, July 2015 Update, and the May 2016 memoranda to examiners) and training examples are consistent with these points.

Sequenom v. Ariosa: On June 27, 2016, the Supreme Court issued an order denying a petition for a writ of certiorari in *Sequenom v. Ariosa*, which leaves in place the Federal Circuit panel decision from June 2015 invalidating Sequenom's method claims as patent ineligible subject matter (788 F.3d 1371 (Fed. Cir. 2015)). In the panel decision, the Federal Circuit applied the two-step framework set out in *Mayo* and *Alice* (Steps 2A and 2B in the USPTO's subject matter eligibility guidance) to determine that the claims were directed to a natural phenomenon (the presence of cffDNA in maternal serum or plasma), and that they did not recite an inventive concept that transforms cffDNA into a patentable invention because the amplifying and detecting steps are routine and conventional (788 F.3d at 1377). While this panel decision is a precedential Federal Circuit panel decision, the denial of the petition for a writ of certiorari does not elevate its significance in this regard.

In summary, the USPTO's current subject matter eligibility guidance and training examples are consistent with the Federal Circuit's panel decisions in *Rapid Litigation Management* and *Sequenom.* Life sciences method claims should continue to be treated in accordance with the USPTO's subject matter eligibility guidance (most recently updated in May of 2016). Questions should be referred to Technology Center subject matter experts or your SPE.