BARTKO ZANKEL BUNZEL REPORT

THE LINE BETWEEN BIO AND TECHNOLOGY: WHILE SUPREME COURT REMAINS SILENT, FEDERAL CIRCUIT PROVIDES MORE POSITIVE GUIDANCE REGARDING PATENTABILITY OF BIOTECHNOLOGY

By Paul Schuck and Sony Barari

The question of what the biotechnology industry can patent ripened into a broad industry debate after two landmark Supreme Court decisions — *Mayo Collaborative Servs v. Prometheus Labs., Inc.* (2012), and *Alice Corp. v. CLS Bank International* (2014). Their collective holding — that under 35 U.S.C. § 101, inherently natural phenomena cannot be patented, even with the addition of previously known secondary technologies — led to the invalidation of numerous patents and likely narrowed the scope of what can be patented in the future. Given the tremendous outlay of capital and effort needed to pursue biotech research, industry leaders worry that this result devalues existing intellectual property portfolios and will disincentivize, and perhaps ultimately curtail, future research and development.

For much of 2016, much of the industry hoped that the Supreme Court would revisit the issue — and presumably ease the standard for patentability — by granting *certiorari* in *Sequenom, Inc. v. Ariosa Diagnostics, Inc*. In *Sequenom,* Judge Susan Illston of the Northern District of California applied the two-step test set forth in *Mayo*: (1) determining whether the claim is directed to a phenomenon of nature; and, if so, (2) determining whether additional claim elements are innovative enough to transform the claim into a patent-eligible application. The court first determined the claims of the patent-in-suit were directed to a phenomenon of nature: the presence of cell free fetal DNA (cffDNA) in a mother's blood plasma. Then, the court found that the additional claim elements were merely the amplification and detection of that cffDNA by common, long-known techniques. While the target of these techniques might be new, the techniques themselves were not — and were not sufficiently inventive to make the claims patentable.

On appeal, the U.S. Court of Appeals for the Federal Circuit, relying on the Supreme Court precedent, unanimously affirmed. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). Sequenom then sought review and modification of the law by the Supreme Court. Many in the industry supported Sequenom. More than 20 groups — including the Biotechnology Innovation Organization (BIO), Pharmaceutical Research and Manufacturers of America, and the Federal Circuit Bar Association — filed *amicus curiae* briefs urging the Court to reconsider and modify the standard set forth in *Mayo* and *Alice*. Similarly, commentators on many leading intellectual property blogs such as Patently-O, IPWatchdog.com, and Patent Docs advocated review of *Ariosa.* Despite the groundswell in favor of review, the Supreme Court denied Sequenom's *writ of certiorari* on June 27, 2016. *Mayo* and *Alice* remained the controlling law without modification or further explanation.

Since this disappointment, however, the Federal Circuit has provided a ray of hope to those in the biotech industry seeking greater patentability. In early July, the Federal Circuit addressed patentability in *Rapid Litigation Mgmt. Ltd, formerly Celsis Holdings, Inc. v. CellzDirect, Inc.* (July 5, 2016). The inventors of the patent-in-suit determined that some hepatocytes — generally unstable liver cells useful for diagnostic and therapeutic purposes — could be frozen and refrozen and still remain viable. Further, by selecting cells that were viable after a first freezing, the scientists could cultivate a sample of cells capable of surviving repeated freezings. Finally, by mixing resilient cells from different sources, the inventors could create a stable, pooled hepatocyte product with a number of uses for researchers. Accordingly, the patent-in-suit claimed both the process of refreezing hepatocytes as well as creating a product with cells from different sources.

The district court, however, ruled that the claims were ultimately directed to the natural phenomenon that hepatocytes could be frozen, and that the claimed processes lacked "the requisite inventive concept" because the inventors "simply 'reapplied the well-understood freezing process.'" Thus, under the *Mayo* test, the asserted claims were held invalid.

But in a departure from the recent trend of invalidation under Section 101, the Federal Circuit reversed on appeal. Without specifically addressing whether the ability of hepatocyte cells to withstand freezing is a "natural law," the appellate panel focused instead on the steps of freezing, selecting, refreezing and pooling of samples. The court concluded that the process went beyond the simple application of a well-known techniques (*e.g.*, freezing) and that the claims as a whole were "directed to a new and useful laboratory technique." The Federal Circuit held that these process achieved "'a new and useful end,' [and] is precisely the type of claim that is eligible for patent."

By focusing on the process itself and not the nature of the underlying cells, the Federal Circuit distinguished *Celsis* from recent Section 101 cases — such as *Alice*, *Ariosa*, *Genetic Technologies v. Merial L.L.C.*, 15-1202, 1203 (Fed. Cir. 2016), and *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 7755 (Fed. Cir. 2014) — in which the asserted patent claims lacked sufficient invention *beyond* a natural phenomenon.

This approach in the biotech context echoes the Federal Circuit's recent approach to patents for computer technology. In *Bascom Internet Servs., Inc. v. AT&T Mobility,* 2016 WL 3514158 (Fed. Cir. June 27, 2016), the court found that the patent-in-suit was directed to an abstract idea. However, applying the second step of the *Alice/Mayo* test, the court found sufficient inventive concept for patentability under Section 101 in the patent's process for filtering internet content. The Federal Circuit noted that "an inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces."

By upholding patents under the second part of the *Mayo* test — *i.e.*, whether there is an inventive concept beyond the related natural phenomena — the Federal Circuit has provided a path forward for would-be biotech patentees. Inventors who make breakthrough discoveries must focus on patenting new and innovative techniques for taking advantage of those discoveries rather than the discoveries themselves. In other

words, would-be inventors must recognize the line between biology (or natural phenomena) and technology (methodology for using, analyzing or manipulating the natural phenomena). While this may be too little too late to save a number of existing biotech patents from invalidation, it does suggest a path for patenting biotech inventions in the post-*Mayo* world.

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