Federal Circuit's Holding on Patent Eligibility for Engineered Host Cells Dovetails With PERA

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PRACTICES Life Sciences, Patents, Patent Prosecution and Counseling, Biotechnology, Intellectual Property

U.S. Supreme Court opinions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[1], *Association for Molecular Pathology v. Myriad Genetics, Inc.*[2] and *Alice Corporation Pty. Ltd. V. CLS Bank International et al*.[3], have left the Court of Appeals for the Federal Circuit grappling with the metes and bounds of patent subject matter eligibility, including the eligibility of nucleic acid sequences.

The United States Court of Appeals for the Federal Circuit ("Federal Circuit") recently issued a holding in *REGENXBIO, Inc. v. Sarepta Therapeutics, Inc.*, No. 24-01408 (Fed. Cir. 2026) that would be consistent with the intent of the **Patent Eligibility Restoration Act of 2025 ("PERA"; S. 1546/H.R. 3152)**. Returning to the holdings of the seminal 1980 Supreme Court *Chakrabarty* case[4], the Federal Circuit held that REGENXBIO's claims to a host cell containing a nucleic acid molecule encoding an adeno-associated virus (AAV) capsid protein and **a heterologous non-AAV** sequence were patent eligible under 35 U.S.C. § 101. Rather than overly broadly applying the holdings of the *Myriad*[5] case, the Federal Circuit instead looked to its holding that "cDNA is not a 'product of nature' and is patent eligible under § 101…"

REGENXBIO had sued Sarepta for infringement of U.S. Patent No. 10,526,617 ("the '617 patent"), which included the following independent claim:

1. A cultured host cell containing a recombinant nucleic acid molecule encoding an AAV vp1 capsid protein having a sequence comprising amino acids 1 to 738 of SEQ ID NO: 81 (AAVrh.10) or a sequence at least 95 percent identical to the full length of amino acids 1 to 738 of SEQ ID NO: 81, wherein the recombinant nucleic acid molecule further comprises a heterologous non-AAV sequence.

Sarepta countered by moving for summary judgment that REGENXBIO's asserted claims were ineligible for patenting under 35 U.S.C. § 101, and REGENXBIO similarly moved that they were not.

The district court had concluded that the '617 claims recited natural products and that the *Chakrabarty* and *Myriad* cases held that there needed to be a material change in what was claimed versus what was found in nature, and that the nucleic acid components in the asserted claims had not been changed, only combined. The district court maintained that the '617 claims were more similar to those in *Funk Brothers*[6], where different species of bacteria that were not inhibitory of each other, were combined as an inoculation for seeds.

Distinguishing the *Funk Brothers* case, the Federal Circuit noted:

"In contrast, the claims here are not merely directed to repackaging products of nature. Genetically engineering two nucleic acid sequence from separate species into a single molecule and then transforming a host cell in order to incorporate that new molecule into it—thus fundamentally creating a cell containing a molecule that could not form in nature on its own—is materially different from growing more than one naturally occurring bacteria strain in a culture where none of the bacteria undergo any change from their natural state." Opinion at 14-15.

Taking the 101 analysis one step further, the Federal Circuit held that a further consideration was "whether the claimed composition has 'the potential for significant utility' even if that utility is only implicit – as it clearly is here." Opinion at 17.

The *REGENXBIO, Inc. v. Sarepta Therapeutics, Inc.* case is a welcome return to a balanced consideration of the scope and intent of 35 U.S.C. 101. Arguably, it is also consistent with the **PERA, which was reintroduced into the Senate on May 1, 2025,** by Senator Thom Tillis. PERA aims to address patent eligibility uncertainly by replacing judicial exceptions with specific statutory exclusions, making it clear – in this instance – that nucleic acids and other compounds should be patent-eligible if in a different form than how they occur in nature. Conversely, PERA seeks to achieve an appropriate and predictable balance by codifying that anything that occurs in nature wholly independent and prior to human activity, should not be eligible for patenting. A Congressional hearing on PERA was held on Oct. 8, 2025, and Senator Tillis is anxious to see the bill passed before his retirement from the Senate at the end of 2026.

As we head to publishing, Sarepta has recently filed a petition for *en banc* rehearing arguing that sequences in the DNA construct in REGENXBIO's host cell exist in nature without manipulation by human activity and therefore are not eligible for patenting. Sarepta argues that the Federal Circuit decision in would allow the patenting of "routine laboratory steps" resulting in the "monopolization of a fundamental tool of research and development in the field of biotechnology…." The conflicting positions between Sarepta and the Federal Circuit decision are precisely what has led to the unpredictability in what can and cannot be patented. This highlights the need for PERA to define these important issues through sound legislation.

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[1] 566 U.S. 66 (2012).

[2] 569 U.S. 576 (2013).

[3] *573 U.S. 208 (2014*).

[4] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

[5] *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

[6] *Funk Brothers Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127 (1948).