The Precedent: Federal Circuit Upholds Gene Therapy Host Cell Claims Under 35 U.S. C. § 101 in *Regenxbio Inc., Et Al. v. Sarepta Therapeutics, Inc., Et Al.*

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In this edition of *The Precedent*, we outline the decision in *Regenxbio Inc., Et Al. v. Sarepta Therapeutics, Inc. Et Al.*

Overview

In *Regenxbio Inc., et al. v. Sarepta Therapeutics, Inc., et al.*, No. 2024-1408, 2026 U.S. App. LEXIS 5011 (Fed. Cir. Feb. 20, 2026), the Federal Circuit reversed a district court's summary judgment that claims directed to host cells containing recombinant nucleic acid molecules were patent ineligible under 35 U.S.C. § 101. Applying the Supreme Court's *Chakrabarty* and *Myriad* decisions, the Federal Circuit held that the claimed host cells contain a recombinant nucleic acid molecule that is markedly different from anything occurring in nature and therefore the claims are not directed to ineligible naturally occurring subject matter.

Issues

1. Are the asserted claims to cultured host cells containing recombinant nucleic acid patent-ineligible under 35 U.S.C. § 101 because they are directed to natural phenomena?
2. If a court determines the patent-eligibility of claims under the Supreme Court of The United States' *Chakrabarty* markedly different characteristics test, does it need to reach the *Alice/Mayo* two-step framework regarding whether claims are directed to a product of nature and recite an inventive concept?

Holdings

1. The asserted claims are directed to human-engineered host cells containing recombinant nucleic acid molecules that do not and cannot exist in nature, even though the molecule is a combination

of two naturally occurring phenomena and thus are not claims to a product of nature.

2. After determining a claimed invention is markedly different from anything occurring in nature, the Court's inquiry can end without resort to the *Alice/Mayo* Nonetheless, even under the *Alice/Mayo* framework, the Federal Circuit held the claims at issue are not directed to a product of nature for the same reasons as under the *Chakrabarty* analysis and the Court need not determine under step two whether they recite an inventive concept.

Background and Reasoning

Regenxbio and the University of Pennsylvania asserted a patent directed to recombinant host cells used in gene therapy. The claimed cells contain nucleic acid encoding a specific adeno-associated virus capsid protein (AAV rh.10) and a heterologous non-AAV sequence. "Heterologous" here means that the non-AAV sequence comes from a different species than the viral sequence. The nucleic acid in the host cell is "recombinant," meaning it was created in the lab by splicing together genetic material from two different organisms, then introducing that combined molecule into the cell.

Regenxbio accused Sarepta of infringing several of its claims by using an AAV variant in cultured host cells for gene therapy. The district court granted summary judgment for Sarepta, holding the claims were ineligible under 35 U.S.C. § 101 because they merely combined two natural components (an AAV sequence and another naturally occurring sequence) and put them in a host cell. On appeal, the Federal Circuit framed the analysis under the Supreme Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 576 (2013), which asks whether a claimed composition has "markedly different characteristics" from what exists in nature and has "the potential for significant utility."

The Federal Circuit used Regenxbio's Claim 1 as illustrative: "1. A cultured host cell containing a recombinant nucleic acid molecule encoding an AAV vp1 capsid protein . . . , wherein the recombinant nucleic acid molecule further comprises a heterologous non-AAV sequence." It was undisputed that the resulting cultured host cells required by the claims are human made and do not exist in nature.

The Federal Circuit explained this situation is analogous to *Chakrabarty*, where the claimed microorganism was a bacterium that had been genetically engineered to contain multiple plasmids. Although the individual plasmids were naturally occurring, their combination in a single organism created a "nonnaturally occurring" composition with new characteristics. The Court contrasted the claims to those in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) and certain claims in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), where the composition claims at issue simply packaged existing natural material together or claimed isolated DNA segments without creating a new molecule or organism.

The Federal Circuit concluded that Regenxbio's claimed host cells are closer to the *Chakrabarty* bacterium and to the cDNA claims in *Myriad* than to the ineligible claims in *Funk Brothers* or *Myriad*'s isolated DNA claims. It reasoned that the recombinant nucleic acid in Regenxbio's claims is "not nature's handiwork" and "could not form in nature on its own" because it joins genetic material from different species into a single molecule. The host cells containing that molecule are a "product of human ingenuity" with significant utility in gene therapy for delivering therapeutic genes to patients.

Sarepta argued, and the district court agreed, that because both the AAV capsid sequence and the heterologous sequence could be found in nature separately, combining them did not make them patent-eligible under Section 101. The Federal Circuit found the district court's analysis too narrow because it focused on "whether the individual components of the claim were markedly different from what is naturally occurring and failed to consider whether the claim composition as a whole was 'not naturally occurring.'"

The Federal Circuit also noted that, unlike in *Funk Brothers*, the claimed composition has a specific and important utility in gene therapy. This further supports eligibility under *Chakrabarty*'s "markedly different characteristics and significant utility" formulation, though the court made clear that the new composition itself is the primary basis for eligibility.

Finally, the Federal Circuit held its inquiry could end without consideration of the *Alice/Mayo* two-step framework regarding whether claims (1) are directed to a product of nature and (2) recite an inventive concept. It explained that, even if resorting to the *Alice/Mayo* framework was necessary, then at step one it would conclude the asserted claims are not directed to a product of nature for the same reasons as under the *Chakrabarty* analysis and therefore there was no need to look for an "inventive concept" under step two. The Federal Circuit therefore reversed the district court's summary judgment of ineligibility and remanded for further proceedings.

Takeaway

Recombinant biological inventions can still be patent-eligible even when they incorporate naturally occurring sequences. What matters is whether the claimed composition, as a whole, is a nonnaturally occurring product created by human intervention and whether it has markedly different characteristics and utility from anything in nature. Drafting claims that clearly identify such recombinant constructs and their engineered host cells can be critical to surviving Section 101 challenges.