

Federal Circuit Provides Guidance on Patentability of Recombinant Host Cells

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On Feb. 20, 2026, the United States Court of Appeals for the Federal Circuit (“Federal Circuit”) issued a thoughtful analysis of biotechnology subject-matter eligibility in *REGENXBIO, Inc. v. Sarepta Therapeutics, Inc.*, No. 24-01408 (Fed. Cir. 2026). Returning to the holdings of the seminal 1980 Supreme Court case of *Chakrabarty*¹, 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 was patent eligible under 35 U.S.C. 101. Rather than overly broadly applying the holdings of the *Myriad*² case, the Federal Circuit instead looked to its holding that “cDNA is not a ‘product of nature’ and is patent eligible under § 101”

In 2020, REGENXBIO initiated a patent infringement lawsuit against Sarepta for infringement of claims 1-9, 12, 15 and 18-25 of U.S. Patent No. 10,526,617 (“the ‘617 Patent”). Independent patent claim 1 is as follows:

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% 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.

Both parties moved for summary judgment on whether the asserted claims were patent eligible under 35 U.S.C. § 101.

In its 2024 decision, the District Court 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, but only combined. The District Court maintained that the ‘617 claims were more similar to those in the *Funk Brothers*³ decision, 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.

Ultimately, the Federal Circuit relied heavily on the facts of *Chakrabarty* wherein “the inventors transferred four different plasmids, each of which were naturally occurring and capable of degrading

four different oil components, into a naturally occurring bacterium. While the inventors genetically modified the four plasmids to combine them, there is no indication that the four plasmids transferred into the host bacterium were otherwise themselves genetically engineered.” Opinion at 15.

The court ultimately held that: “[l]ike the man-made plasmid combining four naturally occurring bacteria in *Chakrabarty*, the claimed nucleic acid molecules here, although containing naturally occurring segments of DNA, are ‘not nature’s handiwork’ and ‘not . . . a hitherto unknown natural phenomenon, but . . . a nonnaturally occurring manufacture or composition of matter.’” Opinion at 13.

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.

This case provides solid guidance on the patent eligibility of recombinant cells, which are a key resource for the biotechnology industry.

¹ *Diamond v. Chakrabarty*, 447 U.S. 303(1980).

² *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

³ *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).