

REGENXBIO INC. v. SAREPTA THERAPEUTICS, INC., Appeal No. 2024-1408 (Fed. Cir. February 20, 2026). Before Dyk, Hughes, and Stoll. Appealed from D. Del. (Judge Andrews).

Background:

REGENXBIO sued Sarepta alleging infringement of claims directed to a cultured host cell containing a recombinant nucleic acid molecule encoding an adeno-associated virus (AAV) protein and further comprising a heterologous non-AAV sequence.

In gene therapy, AAV vectors can be used to deliver a therapeutic gene to replace a defective or missing gene. A heterologous sequence is a nucleic acid sequence that comes from a different species. The AAV-based construct of the patent at issue has properties of non-pathogenicity, broad infectivity, and site-specificity. REGENXBIO and Sarepta agreed that there were no underlying factual disputes regarding eligibility, and both moved for summary judgment on whether the asserted claims were eligible under 35 U.S.C. § 101.

The district court granted Sarepta’s motion and held the claims ineligible. The district court held that taking two naturally occurring sequences (“AAV” and “non-AAV”) from two different organisms (“heterologous”) and putting them together was analogous to the claims found ineligible in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), in which two strains of bacteria were mixed together. The district court determined that none of the individual naturally occurring components had been changed and that combining natural products did not establish patent eligibility. REGENXBIO appealed to the Federal Circuit.

Issues/Holdings:

Did the district court err in its determination that the claims were ineligible as directed to natural phenomena? Yes.

Discussion:

The Federal Circuit considered whether the claimed host cells have “markedly different characteristics” and “the potential for significant utility” compared to what is naturally occurring, relying on *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). The Federal Circuit held that a “recombinant” nucleic acid is artificially manipulated through gene splicing and that a sequence comprising a “heterologous” non-AAV sequence requires splicing by human intervention, thereby demonstrating “markedly different characteristics.” The district court erred in analogizing the claims to *Funk Brothers* because the host cells do not merely repackage products of nature. The Federal Circuit stated that the district court too narrowly considered whether individual components were markedly different from what is naturally occurring and failed to consider whether the claim as a whole was not naturally occurring.

The Federal Circuit also held that the claimed host cells have the potential for significant utility because the parties did not dispute that the constructs are beneficial for gene delivery to selected host cells and gene therapy patients, whereas the composition in *Funk Brothers* functioned no differently whether packaged together or separately. Notably, the Federal Circuit also held that the patent eligibility analysis “may consider whether the claimed composition has the potential for significant utility even if that utility is only implicit.”

Since the claims at issue are eligible under 35 U.S.C. § 101, the Federal Circuit reversed the summary judgment of ineligibility and remanded for further proceedings.