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Federal Circuit Sheds Light on Patent Eligibility for Gene Therapy Patents in Precedential REGENXBIO Decision

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On February 20, 2026, the US Court of Appeals for the Federal Circuit issued a precedential decision in *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*, holding that claims directed at an "undisputedly human made" host cell containing recombinant nucleic acid molecules are patent eligible under §101 (2026 WL 479224 (Fed. Cir. Feb. 20, 2026)). The Federal Circuit reversed the US District Court for the District of Delaware's summary judgment decision holding that the claims were patent ineligible because they were directed at naturally occurring subject matter and remanded the case back to the district court.

The Federal Circuit's analysis in the *REGENXBIO* decision provides the latest guidance on patent eligibility for claims related to life sciences inventions, such as recombinantly engineered cells.

Background

Mutations or deletions in sequences of nucleotides in DNA can cause genetic disorders. Such disorders can be treated by using gene therapy that can deliver a new therapeutic gene to replace the defective or missing gene by using modified virus "vectors," or "host cells." REGENXBIO's patent at issue, US Patent No. 10,526,617, is directed to genetically engineered host cells that contain a recombinant nucleic acid molecule, which was created by "chemically splicing together nucleic acid sequences from two different organisms" (*REGENXBIO*, 2026 WL 479224, at *1-2).

In the district court, both parties moved for summary judgment of patent eligibility under §101. Under §101, only a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" is patent eligible (35 USC §101). Patent claims cannot be granted for "[l]aws of nature, natural phenomena, and abstract ideas" (*Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 US 66, 70 (2012) (citations omitted)).

The district court held that the REGENXBIO patent claimed subject matter that was not eligible for patenting because it covered a combination of genetic elements, each naturally occurring, that were combined in a host cell, without any other alteration. The district court reasoned that, "taking two sequences from two different organisms and put[ting] them together is no different than taking two strains of bacteria and mixing them together," analogizing the claims to those found invalid under §101 in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 US 127 (1948) (*REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*, No. CV 20-1226-RGA, 2024 WL 68278, at *5 (D. Del. Jan. 5, 2024) (cleaned up)).

The district court further found that the invention did not claim any inventive concept under step two of the *Alice/Mayo* test. Under the *Alice/Mayo* framework, a court must first determine whether the invention claims "[l]aws of nature, natural phenomena, and abstract ideas," which are not patentable (*Mayo Collaborative Servs.* 566 US at 70). If the invention is found to be unpatentable in step one, the court must then determine whether the invention contains "an inventive concept sufficient to transform the claimed abstract idea into a patent-eligible application" (*Alice Corp. Pty. v. CLS Bank Int'l*, 573 US 208, 221 (2014) (cleaned up) (citing Mayo, 566 US 66, 82)). Applying that framework, the district court determined that, "the claimed invention is made using well-understood, routine, and conventional steps" (*REGENXBIO*, 2024 WL 68278, at *6).

REGENXBIO appealed, arguing that the asserted claims are patent eligible for having "markedly different" characteristics from any natural product (*REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*, No. 2024-1408, Dkt. 15, at 19-20 (Fed. Cir. May 8, 2024)). The Parker Institute for Cancer Immunotherapy, the J. David Gladstone Institutes and the Dana-Farber Cancer Institute also filed an amicus brief in support of REGENXBIO. As nonprofit cancer research organizations, the amici stated their interest in ensuring that engineered biologic inventions

remain eligible for patent protection, due to their potential to revolutionize medical research, and asserted that the district court's decision injected "significant uncertainty" that could "seriously hinder critical advances in biotechnology" (*REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*, No. 2024-1408, Dkt. 27, at 4-5 (Fed. Cir. May 15, 2024)).

Federal Circuit review against the backdrop of §101 case law

In reversing the district court's summary judgment finding, the Federal Circuit analyzed a line of key §101 cases involving life sciences subject matter: *Diamond v. Chakrabarty*, 447 US 303 (1980); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 US 127 (1948); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 US 576 (2013); and ChromaDex, Inc. v. Elysium Health, Inc., 59 F.4th 1280 (Fed. Cir. 2023). In distinguishing the claims at issue from claims that had been found ineligible, the Federal Circuit provided some guidance on how to apply the "markedly different" test from *Chakrabarty*.

In *Chakrabarty*, the court held patent-eligible claims directed to a "genetically engineered bacterium that possessed the advantage of being 'capable of breaking down multiple components of crude oil'" (*REGENXBIO*, 2026 WL 479224, at *3). The *Chakrabarty* decision reasoned that, "[n]o naturally occurring bacteria possessed the same property for breaking down crude oil" (Id. at *4). Thus, the patentee was found to have "produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility" (*Diamond v. Chakrabarty*, 447 US 303, 310 (1980)).

By contrast, in *Funk Brothers*, the claims at issue were found to be patent ineligible. The claims were directed to "a mixed culture capable of inoculating the seeds of leguminous plants," based on the discovery that "there existed in nature certain species of root-nodule bacteria which did not exert a mutually inhibitive effect on each other" (*REGENXBIO*, 2026 WL 479224, at *4). The *Funk Brothers* decision explained that, "[t]he combination of species produces no new bacteria, no change in the [] species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had … They serve the ends nature originally provided and act quite independently of any effort of the patentee" (*Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 US 127, 131 (1948)). The court in *Chakrabarty* distinguished Funk Brothers by emphasizing that, in *Chakrabarty*, "the patentee's discovery is not nature's handiwork, but his own" (*REGENXBIO*, 2026 WL 479224, at *4 (cleaned up) (quoting *Chakrabarty*, 447 US at 310)).

Myriad was a mixed opinion, finding one set of claims patent ineligible and another set patent eligible. The first set of claims, directed to isolating an individual's BRCA1 and BRCA2 genes, was found to be patent ineligible. The court found that it was "undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA" (*Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 US 576, 590 (2013)). The court distinguished the invention from *Chakrabarty*'s invention, because unlike in Chakrabarty, "Myriad did not create anything" (Id.). Instead, it was analogous to Funk Brothers, because the claimed invention was discovery of the location of the BRCA1 and BRCA2, and that discovery itself did not render the invention a "new composition of matter" (Id. at 591 (cleaned up)).

On the other hand, the court found that the second set of claims directed to isolating the BRCA1 and BRCA2 genes were patent eligible because they included "creation of a cDNA sequence from mRNA [which] results in an exons-only molecule that is not naturally occurring," observing that, "the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived" (Id. at 594-95).

Finally, in *ChromaDex*, the court found patent ineligible claims directed to isolating a vitamin found in milk and combining it with other elements found in milk. Although the claims at issue also claimed an increase in NAD+ biosynthesis, this did not provide characteristics "markedly different" from milk. Because natural milk has NAD+ biosynthesis, "the asserted claims do not require any minimum quantity of the isolated NR vitamin, and the claims do not attribute the claimed increase in NAD+ biosynthesis to the isolated vitamin NR" (*REGENXBIO*, 2026 WL 479224, at *5).

The Federal Circuit reverses district court's summary

judgment finding

Following the guidance of *Chakrabarty*, the Federal Circuit addressed the question of "whether the claimed host cells have 'markedly different characteristics' and have 'the potential for significant utility' from that which is naturally occurring" (*REGENXBIO*, 2026 WL 479224, at *6). The court concluded that the claimed host cells are "markedly different" from anything naturally occurring because, like in *Chakrabarty*, the claimed nucleic acid molecules were "not nature's handiwork," and, like in *Myriad*, "the lab technician unquestionably creates something new" by splicing together the nucleic acid sequences from different organisms (Id. at *6). Here, the court found that:

> Genetically engineering two nucleic acid sequences 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. (Id. at *7)

The Federal Circuit criticized the district court for apparently applying the "markedly different" test to the individual components of each nucleic acid sequence and the host cell, rather than looking at whether the claimed composition, as a whole, was naturally occurring (Id.). The fact that the host cells – rather than these individual components –claimed by the REGENXBIO patents do not and could not occur in nature was critical in concluding that the claimed host cell was not directed to ineligible naturally occurring subject matter (Id. at *9).

Lastly, while not a part of the "markedly different" test, the Federal Circuit also noted that "the potential for significant utility" may be considered. The court here found that the claimed composition "clearly" had the potential for significant utility, because "unlike [the individual, isolated] sequences on their own, various embodiments of the claimed compositions 'are beneficial for gene delivery to selected host cells and gene therapy patients'" (*REGENXBIO*, 2026 WL 479224, at *7 (quoting the asserted patent)).

Conclusion

The *REGENXBIO* decision provides clarity on the patent eligibility of life sciences inventions, reinforcing that human-made constructs and cell lines that do not occur in nature and that display characteristics that are not naturally occurring may satisfy §101.

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