No. 24-1408

United States Court of Appeals for the Federal Circuit

REGENXBIO INC., THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,

Plaintiffs-Appellants,

v.

SAREPTA THERAPEUTICS, INC., SAREPTA THERAPEUTICS THREE, LLC,

Defendants-Appellees.

Appeal from the United States District Court for the District of Delaware
No. 1:20-cv-01226-RGA, Hon. Richard G. Andrews

BRIEF OF THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY AND REVERSAL

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 24-1408

Short Case Caption REGENXBIO Inc. v. Sarepta Therapeutics, Inc.

Filing Party/Entity American Intellectual Property Law Association

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1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☐ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☑ None/Not Applicable
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4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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INTEREST OF *AMICUS CURIAE*

The American Intellectual Property Law Association ("AIPLA") is a national bar association representing the interests of approximately 7,000 members engaged in private and corporate practice, government service, and academia. AIPLA's members represent a diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trade secret, trademark, and copyright law, as well as other fields of law relating to intellectual property. AIPLA's members represent both owners and users of intellectual property. AIPLA's mission includes providing courts with objective analyses to promote an intellectual property system that stimulates and rewards invention, creativity, and investment while accommodating the public's interest in healthy competition, reasonable costs, and basic fairness. AIPLA has no stake in either of the parties to this litigation or the result of this case. AIPLA's only interest is in seeking correct and consistent interpretation of the law as it relates to intellectual property issues.[1]

Pursuant to Federal Rule of Appellate Procedure 29(a)(2), all parties consented to the filing of this brief.

[1] No person, party, or party's counsel, other than AIPLA or its counsel, authored this brief in whole or in part, or contributed money that was intended to fund preparing or submitting this brief.

INTRODUCTION

Biotechnology's promise lies in harnessing components taken from nature and using them for human benefit. For over a century, innovators have leveraged discoveries in the natural world to create breakthrough inventions that have measurably improved human wellbeing, from biofortified foods that have reduced malnutrition and disease to antibiotics that save millions of lives each year. Undergirding the field of biotechnology is the patent system, which "strikes a delicate balance between creating incentives that lead to creation, invention, and discovery and impeding the flow of information that might permit, indeed spur, invention." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 577 (2013) (internal quotation marks omitted).

The district court's decision threatens to upend patent law's "delicate balance." Since the Supreme Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980), biotech innovators have been able to obtain patent protection for inventions that combine components taken from nature to form new and useful compositions of matter. The district court's decision, however, engrafts an entirely new requirement onto patent eligibility under Section 101. According to the district court, it is no longer sufficient for an inventor to combine products from the natural world to form a new, non-natural composition of matter with the potential for significant utility. Instead, the district court's decision requires that the *individual*

natural components of that invention be "altered" or "changed" from their naturally occurring form. This requirement defies decades of Supreme Court precedent on Section 101, and—if affirmed by this Court—will unravel the field of biotechnology and stifle future innovation.

This Court should reverse the district court's judgment.[2]

ARGUMENT

I. Cultured host cells containing a recombinant nucleic acid molecule are patentable subject matter under Section 101 of the Patent Act

Section 101 of the Patent Act allows the inventor of "any new and useful . . . composition of matter" to obtain patent protection over their discovery. 35 U.S.C. § 101. As the Supreme Court has explained, use of the "expansive" term "composition of matter," modified by the comprehensive "any," indicates Congress's plain intent "that the patent laws . . . be given wide scope." *Chakrabarty*, 447 U.S. at 308. But the breadth of Section 101 is not without limit. The Supreme Court has "long held that [Section 101] contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Myriad*, 569 U.S. at 589 (internal quotation marks omitted).

[2] AIPLA's views are limited to the district court's holding that the asserted claims at issue in this case are directed to unpatentable subject matter under 35 U.S.C. § 101. AIPLA takes no position on whether those claims satisfy the other requirements for patentability in Title 35 of the United States Code.

However, because "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas," *id.* at 589-90 (citation omitted), the Supreme Court has explained that "an *application* of a law of nature" or natural phenomenon "may well be deserving of patent protection," *Diamond v. Diehr*, 450 U.S. 175, 187-88 (1981) (emphasis in original). Thus, the Supreme Court has long held that a composition of matter that combines components taken from nature is eligible for patent protection so long as the resulting invention possesses "markedly different characteristics" from anything found in nature and "the potential for significant utility." *Chakrabarty*, 447 U.S. at 310.

A. The '617 Patent's host cells are not found in nature and can be created only by human hands

Genetic disorders—like cystic fibrosis, hemophilia, and sickle cell anemia—are caused by mutations or deletions in the sequences of nucleotides that comprise one's DNA. These sequences are known as "genes." Genetic disorders can cause serious disease or other metabolic dysfunctions that adversely affect human health. Such disorders, and the diseases they cause, traditionally require the use of expensive, chronically administered medications to control symptoms. But the burgeoning field of gene therapy offers an alternative: through use of modified virus "vectors," scientists can deliver a new, therapeutic gene (a "transgene") that replaces the defective or missing gene, treating—and potentially even curing—the disease by addressing the underlying genetic disorder.

Appellant REGENXBIO Inc. develops gene-therapy treatments for diseases using vectors derived from modified adeno-associated viruses ("AAV") to deliver therapeutic genes into patients' cells. The vectors REGENXBIO uses are protected by a number of patents, including United States Patent No. 10,526,617 (the "'617 Patent"), the patent at issue in this case. The '617 Patent covers cultured host cells that are modified to contain a genetically engineered recombinant nucleic acid molecule that encodes for both a particular AAV capsid protein—*i.e.*, the outer shell of the gene therapy viral vector—and for a heterologous non-AAV sequence—*i.e.*, a sequence from a non-AAV source. REGENXBIO uses these cultured host cells to create recombinant AAV vectors for gene therapy to deliver therapeutic transgenes into patients' cells.

Claim 1 of the '617 Patent, which is representative of the asserted claims, recites:

> 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.

The cultured host cells claimed in the '617 Patent are indisputably human-made. There is no evidence—in the record on appeal or otherwise—that the claimed cultured host cells occur in nature. The host cells contain a recombinant nucleic acid molecule that encodes the particular outer shell of the viral vector—an AAV vp 1

capsid protein having a sequence comprising amino acids 1 to 738 of SEQ ID NO: 81 (AAVrh.10)—and a heterologous non-AAV sequence. Cells with these attributes are not found in nature. Indeed, Sarepta's expert witnesses uniformly agreed in the proceedings below that cultured host cells with the features claimed in the '617 Patent are not naturally occurring.

There is likewise no dispute that the recombinant nucleic acid molecule contained within the host cells is non-natural. To be sure, the AAV capsid sequence described in the asserted claims is derived from a natural source: tissue from a rhesus macaque. But that does not make the host cells' recombinant nucleic acid molecules natural. Notably, the naturally derived AAV capsid sequence and the heterologous non-AAV sequence must, according to the claim, be contained within the *same* recombinant nucleic acid molecule. In other words, to fit within the description of this claim, the host cell must contain a single strand of nucleic acids that contains *both* the naturally derived sequence for the AAV capsid protein *and* a different sequence "[d]eriv[ed] from . . . another species or type of organism." *Heterologous*, The Oxford English Dictionary (3d ed. 2017).

The language of the asserted claims further confirms the artificial nature of the recombinant nucleic acid molecule. By definition, "recombinant" genetic material must be "assembled by genetic recombination or genetic engineering." *Recombinant*, The Oxford English Dictionary (3d ed. 2017). And "recombinant

DNA," in particular, refers to DNA that "contains sequences from *different organisms*, esp[ecially] as *produced artificially*." *Recombinant DNA*, The Oxford English Dictionary (3d ed. 2017) (emphasis added). The '617 Patent's "recombinant nucleic acid molecule" thus necessarily refers to a product that—through "genetic engineering"—combines "sequences from different organisms" to create something "artificial[]"—that is, something that is "made or constructed by human skill" or "man-made." *Artificial*, The Oxford English Dictionary (3d ed. 2017).

B. Compositions of matter that are "markedly different" from anything found in nature are patent eligible under Section 101

Despite the clearly artificial, human-made nature of the '617 Patent's cultured host cells, the district court held that they were not patent-eligible subject matter under Section 101. The district court acknowledged that the claimed host cells combined "two sequences from two different organisms." Appx10 (internal quotation marks omitted). But that combination, according to the district court, was insufficient to render the host cells patent eligible because the inventors of the '617 Patent did "not chang[e] any of the claimed invention's naturally occurring components"—*i.e.*, the AAV and non-AAV sequences that comprise the nucleic acid molecule. *Id.* And "[w]ithout some change," the district court concluded, "the mere fact that the '617 patent's inventors combined natural products and put them in a host cell does not make the invention patentable under § 101." *Id.*

The district court's holding misstates controlling Section 101 authority and, in so doing, dramatically expands patent ineligibility under Section 101. Neither the Supreme Court nor this Court requires a patentee to "change" an invention's "naturally occurring components" for it to be patent eligible under Section 101. Instead, as the Supreme Court made clear in *Chakrabarty* and *Myriad*, a manufacture or composition of matter combining naturally derived components is patent eligible if the resulting invention possesses "markedly different characteristics" from anything "found in nature" and "the potential for significant utility." *Chakrabarty*, 447 U.S. at 310; *Myriad*, 569 U.S. at 590-91, 595.

In *Chakrabarty*, the asserted claims were directed to a genetically engineered bacterium capable of breaking down crude oil. 447 U.S. at 305. To create this novel bacterium, the inventors identified four bacteria-derived DNA plasmids—small, circular DNA molecules encoding for specific proteins—each of which "provid[ed] a separate hydrocarbon degradation pathway." *Id.* (internal quotation marks omitted). The inventors then transferred those naturally occurring plasmids into a single *Pseudomonas* bacterium, which itself has no natural capacity to degrade the components of crude oil. *Id.* at 305 n.1. The resulting bacterium was "capable of breaking down multiple components of crude oil," a quality "possessed by no naturally occurring bacteria." *Id.* at 305.

The United States Patent and Trademark Office (the "USPTO") initially rejected Chakrabarty's composition of matter claim for the bacterium. Like the district court here, the patent examiner in *Chakrabarty* concluded that the bacterium was an unpatentable product of nature. *Id.* at 306. But the Supreme Court disagreed. While natural phenomena are unpatentable, the Court explained that Chakrabarty's combination of naturally occurring plasmids in a new bacterium created a "nonnaturally occurring manufacture or composition of matter—a product of human ingenuity having a distinctive name, character and use." *Id.* at 309-10 (internal quotation marks and alteration omitted).

This point was "underscored dramatically," *id.* at 310, by the Court's comparison of the bacterium to the claimed invention in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), in which the patentee sought protection over a mixture of six non-mutually inhibiting root-nodule bacteria that could be used to inoculate the seeds of leguminous plants. Unlike the invention in *Funk Brothers*—a mere "combination of species" that "produc[ed] no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility," *Chakrabarty*, 447 U.S. at 310—Chakrabarty had "produced a new bacterium with markedly different characteristics from any found in nature" and with "the potential for significant utility." *Id*. As such, the invention was "not nature's handiwork, but his own," and was therefore patentable subject matter under Section 101. *Id.*

The Supreme Court affirmed and extended *Chakrabarty*'s Section 101 analysis in *Myriad*. In *Myriad*, the Court considered whether isolated DNA sequences and complementary DNA (cDNA)—a form of synthetic, human-made DNA containing only amino acid-encoding nucleotides (exons) and omitting non-encoding nucleotides (introns)—were patent eligible under Section 101. The Court held that the isolated DNA sequences were not patent eligible because the act of isolating the DNA sequences did not "create anything" new. *Id.* at 591 ("[Myriad] found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.").

cDNA, however, did "not present the same obstacles to patentability as naturally occurring, isolated DNA segments" because "creation of a cDNA sequence . . . results in an exons-only molecule *that is not naturally occurring.*" *Id.* at 594 (emphasis added). To be sure, the inventors in *Myriad* did not "alter" or "change" the cDNA's naturally occurring exon sequences. But the act of removing the introns—leaving a non-natural, exons-only sequence—created a patent-eligible composition of matter because:

> 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. As a result, cDNA is not a "product of nature" and is patent eligible under § 101 . . . .

Id. at 595 (emphasis added).

C. The ’617 Patent’s host cells are patent eligible under *Chakrabarty* and *Myriad*

The host cells claimed in the ’617 Patent fit squarely within the Supreme Court’s Section 101 analysis in *Chakrabarty* and *Myriad*. The inventor in *Chakrabarty* combined known, unaltered, naturally occurring DNA plasmids to create a single bacterium that did not occur in nature. Similarly, the host cells claimed in the ’617 Patent contain a genetically engineered recombinant nucleic acid molecule that includes both naturally sourced DNA encoding an AAV viral capsid protein, combined with a nucleotide sequence from a non-AAV source. Like the cDNA at issue in *Myriad*, the host cells described in the ’617 Patent contain a genetically engineered nucleic acid sequence that does not exist in nature. But the nucleic acid molecule recited in the ’617 Patent’s claims is even further removed from nature: While the cDNA in *Myriad* was derived entirely from a single DNA source—the only difference being the removal of introns—the ’617 Patent claims a single recombinant nucleic acid molecule combining DNA from two different organisms. The resulting artificial nucleic acid molecule must be incorporated into a single cultured host cell, further differentiating it from its natural sources.

The district court purported to apply *Chakrabarty* and *Myriad*. *See* Appx9-10. According to the district court, the host cells claimed in the ’617 Patent are distinguishable because their inventors—unlike the inventors of the bacterium in *Chakrabarty* and cDNA in *Myriad*—did not “change[] any of the claimed

invention's naturally occurring components." *Id*. But the district court got it backwards: the inventors in *Chakrabarty* and *Myriad* did not "change" their inventions' naturally occurring components. Neither the bacterial DNA plasmids in *Chakrabarty* nor the DNA exons in *Myriad* were altered from their natural state. Instead, the inventors in those cases—like the inventors of the '617 Patent—took naturally occurring components and combined them to form a non-natural product with "markedly different characteristics" from anything "found in nature" that possessed "the potential for significant utility" that their natural components, taken alone, did not. *Chakrabarty*, 447 U.S. at 310.

The district court's reliance on *Funk Brothers* is similarly confused. According to the district court, the '617 Patent's combination of "two sequences from two different organisms . . . is no different than taking two strains of bacteria and mixing them together." Appx10 (internal quotation marks omitted). But *Funk Brothers* itself explains why this analogy is inapt. As the Court explained in that case, the simple mixture of six bacterial strains in one inoculant:

> produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.

333 U.S. at 131. By contrast, the '617 Patent claims a non-natural host cell containing a recombinant nucleic acid molecule with sequences from two different

organisms. This invention is found nowhere in nature, and—thanks to the work of its inventors—performs a function that neither sequence alone in nature, or the host cells without the recombinant nucleic acid, could: the production of recombinant AAV vectors for use in gene therapy. The '617 Patent is thus a far cry from the simple mixture of unmodified, naturally occurring bacteria at issue in *Funk Brothers*.

II. If affirmed, the district court's decision will stifle innovation and put U.S. biotechnology innovators at a competitive disadvantage

The district court's grave misapplication of controlling Section 101 case law is reason enough for reversal. If elevated to Federal Circuit precedent, however, the district court's decision would also likely render a wide array of biotech innovations patent ineligible, which would in turn disincentivize research and innovation and put U.S. biotech innovators at a competitive disadvantage relative to their foreign peers.

A. Numerous biotechnology innovations rely on the type of combination that the district court found patent ineligible

The field of gene therapy has enjoyed considerable progress in recent years, with over 2,500 gene therapy trials currently listed with the National Institutes of Health.[3] Viral vectors have been central to gene therapy's recent success, especially AAVs, which are "an ideal match for gene therapy as they can target a wide range of tissues and trigger only a mild immune response in most cases." Gemma Conroy, *How gene therapy is emerging from its 'dark age,'* Nature Index (Dec. 14, 2022),

[3] *See* National Institutes of Health, https://perma.cc/7P38-WD4H.

https://perma.cc/FR23-TCNU. These qualities make AAVs "safe, versatile and efficient" tools for delivering gene therapy treatments. *Id.* In addition to AAVs, gene therapies also rely on modified lentiviruses and adenoviruses, which introduce therapeutic genes into patients' cells by similar means to AAVs. *See* Joel T. Bulcha et al., *Viral vector platforms within the gene therapy landscape*, 6 Signal Transduction and Targeted Therapy 53 (Feb. 8, 2021), https://perma.cc/86SY-3A6P.

If affirmed, the district court's decision would jeopardize many of the viral-vector platforms upon which gene therapy innovations rely, which employ similar technology to that described in the '617 Patent. Under the logic of the district court's decision, many of the inventions described in these patents likely would not be eligible for patent protection under Section 101 because they do not "alter" or "change" the naturally sourced, viral vector-encoding DNA that they incorporate.

The number of patents directly affected by the district court's decision could well be in the thousands. After the Supreme Court's decision in *Myriad*, the USPTO released interim Section 101 Guidance that included exemplar nucleic acid claims. The Guidance explained that while a claim covering "[i]solated nucleic acid comprising SEQ ID NO: 1" would not be patent eligible, a claim covering "[a] vector comprising the nucleic acid of claim 1 *and* a heterologous nucleic acid sequence" would be patent eligible. *See* PTO Interim 101 Guidance, Nature Based Products and July 2015 Update Appendix 2: Index of Eligibility Examples at 10-11 (emphasis

added). This example of a patent-eligible nucleic acid sequence claim is virtually identical to the description of the nucleic acid molecule in the asserted claims here, and many patent holders inevitably would have followed the USPTO's post-*Myriad* guidance. If affirmed, the district court's decision would likely invalidate these many patents. Such a sweeping loss of patent protection would harm innovation in the gene therapy field by disincentivizing investments in important research.

The harm caused by the district court's decision would not be limited to viral vectors used for gene therapies. Under the district court's logic, *any* invention that incorporates a naturally occurring component, but does not "alter" or "change" it, would potentially be patent ineligible. This describes a wide variety of biotech innovations that incorporate natural components—including technologies used for pharmaceuticals, genetically modified organisms used for agriculture and disease modeling, and technologies used to address environmental pollutants—as well as emerging technologies like organic electronics. Indeed, the inventions at issue in *Chakrabarty* and *Myriad* would not be patent eligible under the logic of the district court's decision. As discussed above, both inventions incorporated natural components—bacteria plasmids in *Chakrabarty,* and gene exons in *Myriad*—but did not "alter" or "change" those individual components from their natural form.

B. Affirmance of the district court's decision would deal a serious blow to U.S. biotech innovators

If affirmed, the district court's decision would also disadvantage U.S. biotech innovators vis-à-vis their foreign competitors and hamper domestic biotech innovation. Major foreign biotech jurisdictions—including Europe, Japan, China, and South Korea—permit the patenting of recombinant molecules and the host cells containing those molecules. Loss of patent protection for recombinant molecules in the United States would create further disunity between the patent regimes of the United States and other major foreign jurisdictions, and would push innovation to firms and research institutions located in jurisdictions offering such protection.

An ongoing natural experiment demonstrates the legitimacy of this concern. Following the Supreme Court's *Myriad* decision in 2012, isolated DNA sequences became patent ineligible under Section 101. *See Myriad,* 569 U.S. 591. In Europe, however, isolated DNA sequences remain patent eligible. *See* European Patent Office, European Patent Convention 352 (17th ed. 2020). The European Patent Office continues to grant patents that claim genes and proteins encoded by specific, isolated nucleotide sequences, allowing patent-holders to pursue innovations derived from these discoveries. Meanwhile, there is evidence that innovators based in the United States have steered research and investment away from potential innovations

that may not be patent eligible under *Myriad*.[4] In fact, some innovators have "begun to explore foregoing [U.S.] domestic patenting in favor of foreign patent protections," and have considered whether to move operations overseas to appear more attractive to prospective investors.[5] Affirming the district court's decision would likely further stifle U.S. biotech innovation and accelerate the migration of biotech firms and innovators to foreign jurisdictions.

CONCLUSION

For the foregoing reasons, AIPLA urges this Court to reverse the district court's judgement.

[4] *See* Novartis, Comments in Response to USPTO's "Patent Eligibility Jurisprudence Study Request for Information" at 4-5, (Oct. 15, 2021), https://perma.cc/M7U3-PHLT; Genentech, RE: Request for Comments Regarding the U.S. Patent and Trademark Office's Patent Eligibility Jurisprudence Study at 4, 11 (Oct. 15, 2021), https://perma.cc/NVC9-JLUH.

[5] Wisconsin Alumni Research Foundation, Response to USPTO Request for Information: Patent Eligibility Jurisprudence Study at 3 (Oct. 15, 2021), https://perma.cc/L8L7-TER2.

Dated: May 10, 2024

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 24-1408

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