United States Court of Appeals for the Federal Circuit

REGENXBIO INC., TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,
Plaintiffs-Appellants

v.

SAREPTA THERAPEUTICS, INC., SAREPTA THERAPEUTICS THREE, LLC,
Defendants-Appellees

2024-1408

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

Decided: February 20, 2026

SUSAN E. MORRISON, Fish & Richardson PC, Wilmington, DE, argued for all plaintiffs-appellants. Plaintiff-appellant REGENXBIO Inc. also represented by DEANNA JEAN REICHEL, Minneapolis, MN.

JULIE S. GOLDEMBERG, Morgan, Lewis & Bockius LLP, Philadelphia, PA, for plaintiff-appellant Trustees of the University of Pennsylvania. Also represented by AMY M. DUDASH, Wilmington, DE.

ROBERT B. WILSON, Quinn Emanuel Urquhart & Sullivan, LLP, New York, NY, argued for defendants-appellees. Also represented by JAMES BAKER, ANASTASIA M. FERNANDS.

Before DYK, HUGHES, and STOLL, *Circuit Judges*.

STOLL, *Circuit Judge*.

REGENXBIO Inc. and The Trustees of the University of Pennsylvania (collectively, "REGENXBIO") filed a patent infringement suit in the United States District Court for the District of Delaware against Sarepta Therapeutics, Inc. and Sarepta Therapeutics Three, LLC for infringing claims 1–9, 12, 15, and 18–25 of U.S. Patent No. 10,526,617. Both parties moved for summary judgment of patent eligibility under 35 U.S.C. § 101. The district court granted Sarepta's motion and held the claims ineligible under § 101 as directed to a natural phenomenon. Because we hold the claims are not directed to a natural phenomenon, we reverse the district court's decision and remand the case for further proceedings.

BACKGROUND

I

Genetic disorders—like cystic fibrosis, hemophilia, and sickle cell anemia—are caused by mutations or deletions in the sequences of nucleotides in one's DNA. Gene therapy allows the use of modified virus "vectors" to deliver a new therapeutic gene (a "transgene") that replaces the defective or missing gene, treating or possibly even curing the disease by addressing the underlying genetic disorder. Host cells can be engineered to contain plasmids, where a plasmid is a circular piece of DNA that is separate from the chromosomes of the host cell, and the plasmid has the desired transgene within it. A host cell can make multiple copies of the plasmid and also proliferate to make more

host cells. Plasmids can contain a capsid sequence, where a capsid is the outer shell of a vector. These plasmids can be purified, collected, and introduced into a mammalian host cell, along with other plasmid DNA, to generate a gene therapy vector.

The '617 patent is titled "Method of Detecting and/or Identifying Adeno-Associated Virus (AAV) Sequences and Isolating Novel Sequences Identified Thereby," and is directed to genetically engineered host cells that contain adeno-associated virus rh.10 sequences. U.S. Patent No. 10,526,617 Title. The Background of the Invention explains that AAVs are nonenveloped viruses with single-stranded DNA. It further explains that "AAV's life cycle includes a latent phase at which AAV genomes, after infection, are site specifically integrated into host chromosomes and an infectious phase in which, following either adenovirus or herpes simplex virus infection, the integrated genomes are subsequently rescued, replicated, and packaged into infectious viruses." *Id.* at col. 1 ll. 31–36. These "properties of non-pathogenicity, broad host range infectivity, . . . and potential site-specific chromosomal integration make AAV an attractive tool for gene transfer." *Id.* at col. 1 ll. 36–40. The Background of the Invention recognizes that "[w]hat are desirable are AAV-based constructs for gene delivery." *Id.* at col. 1 ll. 52–53.

The inventors of the '617 patent sought to develop such constructs and specifically developed "molecules which utilize the novel AAV sequences of the invention, including fragments thereof, for production of molecules useful in delivery of a [transgene comprising a] heterologous gene or other nucleic acid sequences to a target cell." *Id.* at col. 17 ll. 15–19. In pursuit of this, the inventors created host cells that "contain sequences encoding a novel AAV capsid"—and a heterologous non-AAV sequence. *Id.* at col. 17 ll. 36–37; *see also id.* at col. 17 ll. 42–45, col. 18 ll. 19–26.

Claim 1 is representative for the purposes of this appeal:

> 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.

Id. at col. 437 ll. 55–63.

The cultured host cells required by the claims are undisputedly human made. They do not exist in nature. Notably, a recombinant nucleic acid molecule is created by chemically splicing together nucleic acid sequences from two different organisms. Appellants' Br. 5; *see also* Parker Br. 11 (defining recombinant nucleic acids as "combining genetic material from two different sources," which are used "to create new, human-made sequences" (citation omitted)).[1] And, as noted above, the claim term "heterologous" means coming from a different species.

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[1] Amicus brief filed by the Parker Institute for Cancer Immunotherapy, The J. David Gladstone Institutes, and the Dana-Farber Cancer Institute. *See* ECF No. 27. The amici further explain that creating recombinant DNA is a multi-step process: (1) fragments of DNA are created, for example, by using restriction enzymes chosen to cleave DNA at specific sites in order to get the desired fragments; (2) the desired DNA fragments are joined by DNA ligases; (3) the recombinant nucleic acid sequence with the desired DNA fragments is ligated into a plasmid that is used to

II

REGENXBIO accused Sarepta of infringing claims 1–9, 12, 15, and 18–25 of the '617 patent based on Sarepta's use of the AAV variant rh.74 in cultured host cells to make a gene therapy product referred to as SRP-9001, which treats Duchenne muscular dystrophy. *See REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*, No. 20-cv-1226-RGA, 2024 WL 68278, at *1 (D. Del. Jan. 5, 2024). Both parties moved for summary judgment on whether the asserted claims were eligible under 35 U.S.C. § 101. The district court noted that there were no underlying factual disputes pertaining to eligibility in this case and the parties agreed. *REGENXBIO*, 2024 WL 68278, at *3.

The parties debated whether the claims disclose natural products and both analogized this case to *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), in which the Supreme Court considered the eligibility of composition claims under the markedly different characteristics test from *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Neither party asserted that the claims are ineligible as an abstract idea or on any other grounds.

Starting with the markedly different framework from *Chakrabarty*, the district court noted that "[t]he '617 patent's claims disclose natural products, including the rh.10

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transform a host cell; (4) the plasmid is then amplified by growing colonies of the host cells; and (5) after amplification, the recombinant DNA is extracted from the host cell and purified. Parker Br. 12–13 (citations omitted). The transformation of the host cell that occurs at step three allows the cell to take up an exogenous nucleic acid sequence via transfection, which is "the process of artificially introducing nucleic acids (DNA or RNA) into cells." Parker Br. 14–15 (citations omitted).

sequence and a heterologous non-AAV sequence." *REGENXBIO*, 2024 WL 68278, at *4. The district court then posited that in both *Chakrabarty* and *Myriad* the Supreme Court "highlight[ed] the importance of change" between naturally occurring subject matter and the claimed composition. *Id.* at *5. The district court explained that in *Chakrabarty*, "the invention was patentable because the inventor genetically engineered bacteria to make the bacteria 'capable of breaking down multiple components of crude oil.'" *Id.* (quoting *Chakrabarty*, 447 U.S. at 305, 310). Continuing, the district court explained that in *Myriad*, "the inventor removed non-coding regions from naturally occurring DNA sequences to create something new." *Id.* (citing *Myriad*, 569 U.S. at 594–95). Turning to claim 1 of the '617 patent, however, the district court determined that none of the individual naturally occurring components in the claims had been changed and that "combin[ing] natural products and put[ting] them in a host cell does not make the invention patentable under § 101." *Id.*

Instead, the district court determined that the claims here were "similar to the ineligible claims in *Funk Brothers* [*Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)]," because "[t]aking 'two sequences from two different organisms and put[ting] them together' is no different than taking two strains of bacteria and mixing them together." *REGENXBIO*, 2024 WL 68278, at *5 (third alteration in original) (citation omitted). The district court further considered and disregarded that the claimed human-made genetically engineered host cell possessed utility for gene therapy because nothing in the claims discloses use of the recombinant nucleic acid for a particular purpose.

The district court then considered whether the claims recited an inventive concept under step two of the *Alice*/*Mayo* framework. The district court determined the claims lacked an inventive concept and "the claimed invention is made using well-understood, routine, and conventional steps." *Id.* at *6. The district court thus granted

Sarepta's summary judgment motion and held all asserted claims of the '617 patent ineligible under § 101.

REGENXBIO appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review the district court's grant of summary judgment under the law of the regional circuit, here the Third Circuit, which reviews such issues de novo. *Junker v. Med. Components, Inc.*, 25 F.4th 1027, 1032 (Fed. Cir. 2022) (citing *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1306 (Fed. Cir. 2019)). Summary judgment is appropriate when, drawing all reasonable inferences in the nonmoving party's favor, "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Eligibility under § 101 may involve questions of fact but is, ultimately, a question of law that we review de novo. *Nat. Alts. Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1342 (Fed. Cir. 2019); *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1342 (Fed. Cir. 2018).

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. "Laws of nature, natural phenomena, and abstract ideas," in contrast, "are not patentable." *Myriad*, 569 U.S. at 589 (citation omitted). An overview of the Supreme Court's decisions in *Chakrabarty*, *Funk Brothers*, and *Myriad*, as well as our decision in *ChromaDex, Inc. v. Elysium Health, Inc.*, 59 F.4th 1280 (Fed. Cir. 2023), is useful prior to considering REGENXBIO's claims.

In *Chakrabarty*, the Court held eligible claims directed to a genetically engineered bacterium that possessed the

advantage of being "capable of breaking down multiple components of crude oil." 447 U.S. at 305. Illustrative claim 7 recited:

> [7. A] bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

Id. at 305; *see also Application of Chakrabarty*, 571 F.2d 40, 41–42 (CCPA 1978). No naturally occurring bacteria possessed the same property for breaking down crude oil. *Chakrabarty*, 447 U.S. at 305. Accordingly, in the Court's view, the "claim [was] not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity having a distinctive name, character and use." *Id.* at 309–10 (cleaned up) (citation omitted). Because "the patentee ha[d] produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility," the Court upheld the claims. *Id.* at 310.

In *Chakrabarty*, the Court also distinguished the claimed invention from that in *Funk Brothers*. *Id.* The Court explained that, in *Funk Brothers*, "the patentee had discovered that there existed in nature certain species of root-nodule bacteria which did not exert a mutually inhibitive effect on each other" and "used that discovery to produce a mixed culture capable of inoculating the seeds of leguminous plants." *Id.* This was considered ineligible as "only some of the handiwork of nature":

> Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species 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.

Id. (quoting *Funk Bros.*, 333 U.S. at 131). The Court distinguished *Funk Brothers* by emphasizing that, in *Chakrabarty*, the patentee's "discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101." *Id.*

The Court in *Myriad* later looked to both *Chakrabarty* and *Funk Brothers* when considering the eligibility of two sets of claims. The claims in the first set were directed to isolating an individual's BRCA1 and BRCA2 genes: "'[1. A]n isolated DNA coding for a BRCA1 polypeptide,' which has 'the amino acid sequence set forth in SEQ ID NO:2,'" and "SEQ ID NO:2 sets forth a list of 1,863 amino acids that the typical BRCA1 gene encodes." *Myriad*, 569 U.S. at 584 (citation omitted). As to this set of claims, 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." *Id.* at 590. The Court explained that "*Chakrabarty* is central to this inquiry" of eligibility before concluding that "[i]n this case, by contrast [to *Chakrabarty*], Myriad did not create anything." *Id.* at 590–91. Instead, as in *Funk Brothers*, Myriad's claims "fell squarely within the law of nature exception." *Id.* at 591. While "Myriad found the location of the BRCA1 and BRCA2 genes, . . . that discovery, by itself, d[id] not render the BRCA genes 'new . . . composition[s] of matter.'" *Id.* (second alteration and second omission in original) (quoting 35 U.S.C. § 101). The Court was not persuaded by Myriad's reliance on its claims being directed to isolating genes, reasoning that this did not render the

claims eligible because they "are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA." *Id.* at 593.

In contrast to the claims directed to isolating the BRCA1 and BRCA2 genes, the Court held Myriad's second set of claims directed to cDNA eligible. The relevant claim language read, "[2. T]he isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1," where SEQ ID NO:1 sets forth a sequence of cDNA exons in the BRCA1 gene, rather than a full DNA sequence containing both exons and introns.[2] *Id.* at 584 (citation omitted). The Court reasoned that:

> cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. As already explained, *creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring*. Petitioners concede that cDNA differs from natural DNA in that "the non-coding regions have been removed." They nevertheless argue that cDNA is not patent eligible because "[t]he nucleotide sequence of cDNA is dictated by nature, not by the lab technician." That may be so, but *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 . . . .

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[2] "Only some DNA nucleotides . . . code for amino acids; these nucleotides are known as 'exons.' Nucleotides that do not code for amino acids, in contrast, are known as 'introns.'" *Myriad*, 569 U.S. at 581.

Id. at 594–95 (alteration in original) (emphases added) (citations and footnote omitted).

In *ChromaDex*, our court followed *Chakrabarty* and *Myriad* in determining the eligibility of claims directed to the isolation of a vitamin—NR[3]—found in milk. The claims recited "[a] composition comprising . . . isolated [NR]" in combination with other elements also found in milk "wherein said composition . . . increases NAD+[4] biosynthesis upon oral administration." *ChromaDex*, 59 F.4th at 1283 (second alteration in original). In *ChromaDex*, it was undisputed that the only structural difference between the claims and naturally occurring milk was that the NR in the claimed composition was isolated. *Id.* at 1283–84. Our court explained that "*Chakrabarty* defines the inquiry: to be patentable, the claimed composition must 'ha[ve] markedly different characteristics and have the potential for significant utility.'" *Id.* at 1284 (alteration in original) (quoting *Chakrabarty*, 447 U.S. at 310). We held the claims ineligible because "the asserted claims do not have characteristics markedly different from milk." *Id.* The patentee argued that the claimed composition recited a marked difference from natural milk—i.e., that the isolation of the milk vitamin NR allowed for significantly more NAD+ biosynthesis than is found in milk. *Id.* However, the court explained that natural milk has NAD+ biosynthesis (albeit due to a different element in milk, tryptophan), 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

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[3] NR stands for nicotinamide riboside, a form of vitamin B3. *ChromaDex*, 59 F.4th at 1281.

[4] NAD+ stands for the coenzyme nicotinamide adenine dinucleotide. *ChromaDex*, 59 F.4th at 1281. "NAD+ deficiencies can cause diseases in both animals and humans." *Id.*

vitamin NR. *Id.* at 1284–85. The court further analogized the case to the gene isolation claims in *Myriad*, noting that, "[a]s in *Myriad*, . . . the act of isolating the [vitamin] compared to how [it] naturally exists in milk is not sufficient, on its own, to confer patent eligibility." *Id.* at 1284 (citing *Myriad*, 569 U.S. at 590–93). Because "[t]he claimed compositions d[id] not exhibit markedly different characteristics from natural milk[, they were], therefore, invalid for claiming a patent-ineligible product of nature." *Id.*

After focusing on the "'markedly different characteristics' framework for analyzing whether the claimed compositions there were directed to a natural phenomenon," the court in *ChromaDex* noted that "[t]he inquiry could end." *Id.* at 1285. We pointed out that the Supreme Court has "never applied the *Alice*/*Mayo* two-step framework [to such claims,] despite deciding [*Myriad*] after *Mayo*." *Id.* However, we opined that "if resort to *Alice*/*Mayo* is necessary," the claims in *ChromaDex* were directed to a product of nature under step one for the reasons explained in the court's markedly different characteristics analysis. *Id.* We then determined that, under step two, "the claims lack an inventive step because they are directed to nothing more than compositions that increase NAD+ biosynthesis, which is the very natural principle that renders the claims patent-ineligible." *Id.* at 1285–86.

Turning now to the composition claims at issue here, as explained above, *Chakrabarty* defines our inquiry. We thus ask whether the claimed host cells have "markedly different characteristics" and have "the potential for significant utility" from that which is naturally occurring. *Chakrabarty*, 447 U.S. at 310. In answering this inquiry and considering the natural phenomenon exception, we conclude that the claims here are more analogous to the eligible claims in *Chakrabarty* and *Myriad* than the ineligible claims in *Funk Brothers*, *Myriad*, and *ChromaDex*.

It is uncontested that the claimed host cells include a recombinant nucleic acid molecule that does not and cannot exist in nature. Specifically, the claims require (1) "recombinant" nucleic acid, which means segments of nucleic acid from one source are artificially manipulated or inserted into the nucleic acid of another source through gene splicing; and (2) a nucleic acid molecule capable of encoding a sequence at least 95% identical to an AAV rh.10 sequence and a "heterologous" non-AAV sequence, where "heterologous" means from a different species. Thus, the recombinant nucleic acid molecule must be spliced together via human intervention from at least two different species to meet the claim limitations.

Like 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." *Chakrabarty*, 447 U.S. at 309–10. Similarly, like the cDNA claims in *Myriad*, "the lab technician unquestionably creates something new" when she splices together the claimed recombinant nucleic acid molecule that encodes an AAV vp1 capsid protein and a heterologous non-AAV sequence and inserts said molecule into a host cell. *Myriad*, 569 U.S. at 595.

On the other hand, contrary to the district court's holding, the claims here are distinguishable from those in *Funk Brothers*. In concluding that the asserted claims are like those in *Funk Brothers*, the district court found that "[t]aking 'two sequences from two different organisms and put[ting] them together' is no different than taking two strains of bacteria and mixing them together." *REGENXBIO*, 2024 WL 68278, at *5 (second alteration in original) (citation omitted). This analogy is flawed and inconsistent with the undisputed scientific evidence in the

record. The Court in *Funk Brothers* described the issues in the field at the time and the patentee's alleged invention:

> There had been a few mixed cultures for field legumes. But they had proved generally unsatisfactory because the different species of the Rhizobia bacteria produced an inhibitory effect on each other when mixed in a common base, with the result that their efficiency was reduced. Hence it had been assumed that the different species were mutually inhibitive. [The patentee] discovered that there are strains of each species of root-nodule bacteria which do not exert a mutually inhibitive effect on each other. He also ascertained that those mutually non-inhibitive strains can, by certain methods of selection and testing, be isolated and used in mixed cultures. Thus he provided a mixed culture of Rhizobia capable of inoculating the seeds of plants belonging to several cross-inoculation groups.

333 U.S. at 129–30. As the Court pointed out, this may have been an "important commercial advance," but it was no more than an improvement in packaging such that a "farmer need not buy six different packages for six different crops. He can buy one package and use it for any or all of his crops of leguminous plants. And, . . . [this] also h[e]ld advantages for the dealers and manufacturers by reducing inventory problems and the like." *Id.* at 131. But, the Court continued, merely creating this type of commercial advantage does not make something patentable. *See id.* at 132.

In contrast, the claims here are not merely directed to repackaging products of nature. 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.

In concluding otherwise, the district court ignored the Supreme Court's holding in *Chakrabarty*. In *Chakrabarty*, 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. *See Chakrabarty*, 447 U.S. at 305 & n.1. Yet, the Court still determined that the claimed bacterium was "a nonnaturally occurring manufacture or composition of matter—[i.e.,] a product of human ingenuity" that was "markedly different" from the four individual plasmids. *Id.* at 309–10 (citation omitted). *Chakrabarty* thus undercuts the district court's reliance on the fact that "[t]he inventors of the '617 patent . . . have not changed any of the claimed invention's naturally occurring components," like the "rh.10 sequences" and "non-AAV sequence." *REGENXBIO*, 2024 WL 68278, at *5. Moreover, the district court's analysis takes too narrow a view of the asserted claims by focusing on whether the individual components of the claim were markedly different from what is naturally occurring and failing to consider whether the claimed composition as a whole was "not naturally occurring." *Myriad*, 569 U.S. at 594.[5]

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[5] Relatedly, the district court's analysis of claim 20 from *Association for Molecular Pathology v. USPTO*, 689 F.3d 1303 (Fed. Cir. 2012) ("*AMP*"), although brief, similarly contradicts its logic regarding the analogy

Finally, although not required by *Myriad* in its application of *Chakrabarty*, it is undisputed that, unlike the claims in *Funk Brothers*, the claimed composition here has "the potential for significant utility." *Chakrabarty*, 447 U.S. at 310. It is undisputed (and touted in the specification) that, unlike isolated AAV rh.10 sequences and non-AAV sequences on their own, various embodiments of the claimed compositions "are beneficial for gene delivery to selected host cells and gene therapy patients." '617 patent col. 25 ll. 58–62. This is in stark contrast to the claims in *Funk Brothers*, which as the Supreme Court explained, recited a composition of matter that functioned no differently whether packaging the individual components together or separately.

Related to this final point, the parties dispute whether unclaimed functional distinctions between the claimed composition and a naturally occurring cell can be considered as part of the *Chakrabarty* inquiry. The answer to this question is found in *Chakrabarty* itself. As noted above, the Supreme Court in *Chakrabarty* emphasized that no naturally occurring bacteria possessed the same property for breaking down crude oil even though the claims only recited the hydrocarbon-degrading properties of the plasmids contained by the bacterium rather than any

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between the technology at issue here versus *Funk Brothers*. The district court differentiated the claimed host cells from the eligible claim 20 in *AMP*, reasoning that we concluded in *AMP* "that the inventor had altered 'a cell to include a foreign gene, resulting in a man-made, transformed cell with enhanced function and utility.'" *REGENXBIO*, 2024 WL 68278, at *5 n.3 (quoting *AMP*, 689 F.3d at 1335–37). But altering a cell to include foreign sequences via a laboratory-initiated process, and thus creating something man-made, is also what occurs to create the claimed host cells here.

capability of the bacterium itself. *See* 447 U.S. at 305. And the court nonetheless held that, because "the patentee ha[d] produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility," the claims were eligible. *Id.* at 310. Accordingly, the court may consider whether the claimed composition has "the potential for significant utility" even if that utility is only implicit—as it clearly is here.

Sarepta cites *ChromaDex* to support its view to the contrary. But *ChromaDex* does not undermine *Chakrabarty*. The claims in *ChromaDex* expressly required the composition to "increase[] NAD+ biosynthesis." *ChromaDex*, 59 F.4th at 1283. In other words, the claims defined the structure of the composition not just by the identity of its components but also by the overall function of the recited composition. As such, in assessing whether the claims possess markedly different characteristics compared to the natural product(s), this court had to consider this claim limitation. On the other hand, in *Myriad*, the Supreme Court did not analyze function in considering whether the cDNA claims were markedly different from naturally occurring DNA, as the claims did not recite such a function. Instead, the Court only analyzed the recited structural differences between naturally occurring DNA and the claimed cDNA. Here, based on our holding above that the claimed host cells contain molecules that are markedly different from anything naturally occurring, we need not reach the question whether they are markedly different based on unclaimed functions. But even when considering that question, *Chakrabarty* supports holding the claims eligible.

Sarepta further seeks to analogize this case to the ineligible claims in *Myriad*. In doing so, Sarepta does not challenge that the claimed host cells do not and cannot occur in nature. Instead, Sarepta seeks to reframe the claims as directed only to isolating the AAV rh.10 sequence. But the claim language clearly belies this attempt. Claim 1

requires a cultured host cell, a heterologous nucleic acid sequence, and a recombinant nucleic acid molecule that codes for both the heterologous sequence and the AAV rh.10 sequence. Because the claims are not simply directed to isolating a newly discovered nucleic acid sequence, we are not persuaded that the claims here are analogous to ineligible claims in *Myriad*.

Sarepta nonetheless urges us to set aside the claims as a whole and instead focus on isolating the AAV rh.10 sequence alone because the other claim limitations are conventional and would not themselves be patentable advancements. We are not persuaded. Controlling precedent does not direct us to disregard conventional limitations when considering whether claims are "markedly different" from products of nature. *See, e.g.*, *Chakrabarty*, 447 U.S. at 310; *Diamond v. Diehr*, 450 U.S. 175, 188 (1981) ("[I]t [is] inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the [§ 101] analysis."). We decline to read out or ignore limitations in a claim merely because they may be found in the prior art or within the knowledge of a skilled artisan.[6]

Accordingly, the claimed host cells here contain a recombinant nucleic acid molecule that, by definition, is markedly different from anything occurring in nature. The claimed host cells are, therefore, not patent-ineligible claims to naturally occurring subject matter. Like in *ChromaDex*, our inquiry could end here. However, if resort to

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[6] While this may prove material for other inquiries into the validity of the '617 patent, we emphasize that "parties and tribunals [should] not . . . conflate the separate novelty and obviousness inquiries under 35 U.S.C. §§ 102 and 103, respectively, with the step one inquiry under § 101." *PowerBlock Holdings, Inc. v. iFit, Inc.*, 146 F.4th 1366, 1373 n.3 (Fed. Cir. 2025).

the *Alice*/*Mayo* framework is necessary, then at step one we conclude the asserted claims are not directed to a product of nature for the reasons stated above. Because we determine that the claims are not directed to ineligible naturally occurring subject matter at step one, we do not consider step two. *See CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1368 (Fed. Cir. 2020) ("If the claims are not directed to a patent-ineligible concept under *Alice* step [one], 'the claims satisfy § 101 and we need not proceed to the second step.'" (quoting *Data Engine Techs. LLC v. Google LLC*, 906 F.3d 999, 1007 (Fed. Cir. 2018))).

CONCLUSION

We have considered Sarepta's remaining arguments and find them unpersuasive. For the foregoing reasons, we reverse the district court's summary judgment of ineligibility under 35 U.S.C. § 101 and remand for further proceedings consistent with this opinion.

REVERSED AND REMANDED

COSTS

Costs to Appellants.