No. 2024-1408

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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

v.

SAREPTA THERAPEUTICS, INC. and SAREPTA THERAPEUTICS THREE, LLC,
Appellees.

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

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CORRECTED BRIEF OF *AMICUS CURIAE* THE HONORABLE PAUL R. MICHEL (RET.) IN SUPPORT OF APPELLANTS AND REVERSAL

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2024-1408

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

Filing Party/Entity The Honorable Paul R. Michel (Ret.)

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Name: Matthew J. Dowd

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
The Honorable Paul R. Michel (Ret.)		

☐ Additional pages attached

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☐ None/Not Applicable ☐ Additional pages attached

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5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

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☑ None/Not Applicable ☐ Additional pages attached

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Sinclair Refining Co. v. Atkinson,
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35 U.S.C. § 103 17

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Other Authorities

Adam Mossoff, *The U.S. Must Fix Its Innovation Engine: The Patent System*, STAT (Mar. 8, 2022), https://statnews.com/2022/03/08/the-u-s-must-fix-its-innovation-engine-the-patent-system/ 4

Andrei Iancu & Cooper Godfrey, *The Bayh-Dole Act and the Debate Over "Resonable Price" March-In Rights,* FedSoc Blog (April 18, 2024), https://fedsoc.org/commentary/fedsoc-blog/the-bayh-dole-act-and-the-debate-over-reasonable-price-march-in-rights 7

David O. Taylor, *Patent Eligibility and Investment*, 41 Cardozo L. Rev. 2010 (2020) 3

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Paul Michel, *Waiving COVID-19 IP Protections Would Harm US Industry*, Law360 (Jan. 4, 2024), https://www.law360.com/ip/articles/1779536 6

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INTEREST OF *AMICUS CURIAE*[1]

Amicus Curiae Paul R. Michel is a former judge of the U.S. Court of Appeals for the Federal Circuit, appointed in 1988 and serving until 2010, when he retired from the bench as Chief Judge. Since his retirement, *Amicus* has remained active in patent policy discussions, working to help ensure that U.S. patent laws and policy are geared to achieving the proper balance between incentivizing innovation and allowing free-market competition.

The present case is of concern to *Amicus* because the district court's ruling continues a troubling trend of misapplying 35 U.S.C. § 101.

Patent-eligibility law is now denying even the possibility of patent protection for lifesaving medical diagnostic inventions. Patent protection is critical to incentivizing innovation in the field of medical diagnostics, and life-saving diagnostics are precisely the type of innovation that the U.S. patent system should be encouraging. The outcome in this case wrongfully shut the door on patent protection before any evaluation of the claimed invention's merits ever occurred.

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[1] No party's counsel authored this brief in whole or in part, and no party, party's counsel, or any other person contributed money to fund the preparation or submission of this brief. All parties consent to the brief's filing.

SUMMARY OF THE ARGUMENT

This is an easy case.

That is a phrase that should not be used lightly. Too many appellants have come to this Court asserting that their cases are "easy" ones that should be reversed. Of course, most patent appeals are not easy, and district courts generally reach the correct conclusion. But the present appeal is a clear exception to that general rule.

Quite simply, the district court misapplied the statute and misapplied precedent when it held that the claimed genetically engineered cells are not patent eligible under § 101. The court's decision overlooks the plain language of the statute, which allows patents on any "new" "composition of matter." Beyond the statute, the district court's ruling misunderstands controlling precedent of the Supreme Court and this Court. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), itself confirms that Appellants' genetically engineered cells are patent eligible. And later cases, such as *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), only strengthen that conclusion.

ARGUMENT

I. Patent Protection Drives Innovation And Encourages Investments In Lifesaving Technologies

The innovation ecosystem needs robust patent protection for novel technologies that lead to lifesaving medicines and treatments. Robust patent protection encourages the necessary investment so that inventors invent, firms commercialize the inventions, and society benefits.

A. The Importance of Rewarding Inventors and Innovators for their Investment of Time and Money

Study after study confirms that robust and reliable patent protective is a key driver of innovation in the biotechnology and healthcare industries. *See, e.g.*, U.S. Patent and Trademark Office, *Request for Comments: Unlocking the Full Potential of Intellectual Property by Translating More Innovation to the Marketplace*, 89 Fed. Reg. 18,907, 18,907 (Mar. 15, 2024) ("Intellectual property (IP) forms the bridge that moves innovation to impact for the benefit of society."); David O. Taylor, *Patent Eligibility and Investment*, 41 Cardozo L. Rev. 2019, 2094 (2020) (presenting data confirming the "negative effects of the [Supreme] Court's heightened eligibility standard on investment in technological development in the United States").

B. The Current Innovation Ecosystem is Under Assault

Unfortunately, the U.S. innovation ecosystem is under assault. Over the past fifteen years or so, a series of decisions have decimated the U.S. patent system, which has led to increased certainty and decreased investments.

The decline of the U.S. patent system has been well documented elsewhere and need not be repeated here. *See, e.g.*, Adam Mossoff, *The U.S. Must Fix Its Innovation Engine: The Patent System*, STAT (Mar. 8, 2022) ("American innovators are no longer promised reliable and effective rights for the fruits of their labors.")[2]; Paul R. Michel & Matthew J. Dowd, *From a Strong Property Right to a Fickle Government Franchise: The Transformation of the U.S. Patent System in 15 Years*, 69 Drake L. Rev. 1 (2021).

One particularly insidious trend is the declining availability of injunctive relief. *See, e.g.*, Julie Carlson, *New Data Show There Is a Problem with the U.S. Patent System—But It's Not Patent Trolls*, IP Watchdog.com (May 6, 2024) ("The report shows that injunction grants

[2] https://www.statnews.com/2022/03/08/the-u-s-must-fix-its-innovation-engine-the-patent-system/.

(excluding default judgments) have fallen from a peak of 80 in the period 2008 to 2012 to just 36 in the period 2018 to 2022.")[3]; *see also* Paul R. Michel & John T. Battaglia, *eBay, the Right to Exclude, and the Two Classes of Patent Owners*, 2020 Patently-O Patent L. J. 11, 18 (2020) (explaining how "courts over the last decade-plus have instead created the very thing that *eBay* condemned; *viz.*, a 'categorical rule' (or something close to it) that bars NPEs from obtaining injunctions").[4] Indeed, injunctions—particularly preliminary injunctions—have become extraordinarily rare.

Beyond the legal decisions over the past years, dangerous policy proposals have contributed to the weakened status of U.S. patents and the U.S. innovation ecosystem. A steady drumbeat from academics has argued for waiving intellectual property rights for inventions related to treating COVID-19. But there has never been any evidence that any waiver was needed, and eviscerating patent rights would have set a dan-

[3] https://ipwatchdog.com/2024/05/06/new-data-show-problem-us-patent-system-not-patent-trolls/id=176149/.

[4] https://patentlyo.com/media/2020/11/Michel.2020.RightToExclude.pdf.

gerous precedent. *See, e.g.*, Paul Michel, *Waiving COVID-19 IP Protections Would Harm US Industry*, Law360 (Jan. 4, 2024).[5] The irony of the COVID-waiver debate is that almost all the technologies that enabled the rapid development of COVID treatments existed because earlier innovators were rewarded with robust patent rights.

Other dangerous policy arguments have been advanced that will further harm the innovation ecosystem. The current Biden administration has suggested using the Bayh-Dole Act to trample the patent rights of innovators simply for the short-sighted and politically motived objective of lowering drug prices. Paul Michel & Kathleen O'Malley, *White House's Drug Patent Plan Undercuts Research and Innovation*, Bloomberg Law (Jan. 9, 2024) ("[A]llowing the government to void exclusive patent licensing agreements would prove economically devastating.")[6]; *see also* Paul Michel & Kathleen O'Malley, *Biden's Bayh-Dole Act Proposal Misuses "March-In Rights*", The Tribune-Democrat (Apr. 25,

[5] https://www.law360.com/ip/articles/1779536.

[6] https://news.bloomberglaw.com/us-law-week/white-houses-drug-patent-plan-undercuts-research-and-innovation.

2024)[7]; Andrei Iancu & Cooper Godfrey, *The Bayh-Dole Act and the Debate Over "Reasonable Price" March-In Rights*, FedSoc Blog (Apr. 18, 2024) ("Because the Bayh-Dole Act does not clearly authorize the use of march-in rights to control prices, courts will likely conclude that the administration is essentially claiming unbounded power to set prices and relicense patents without any meaningful guidance from Congress.")[8]. The mere threat of misusing the Bayh-Dole Act further weakens the U.S. innovation ecosystem by devaluing patents by placing them under a cloud of uncertainty.

II. The District Court's Decision Is Plainly Wrong Under Settled Precedent

Despite the ongoing damage to the U.S. patent system, the Court need not delve deeply into policy considerations to reach the correct outcome in this appeal. The correct outcome flows from a straightforward application of the statute and precedent.

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[7] https://www.tribdem.com/news/editorials/columns/paul-michel-and-kathleen-omalley-bidens-bayh-dole-act-proposal-misuses-march-in-rights/article_2d9b0cfa-0233-11ef-a25b-03ff478ee734.html.

[8] https://fedsoc.org/commentary/fedsoc-blog/the-bayh-dole-act-and-the-debate-over-reasonable-price-march-in-rights.

A. The Claimed Invention is a "New" "Composition of Matter"

The invention at issue is a novel genetically modified cell. It is not a product of nature. It exists only as the fruits of human innovation. It is precisely the type of invention contemplated by the 1952 Patent Act when "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'" *Chakrabarty*, 447 U.S. at 309 (quoting S. Rep. No. 82-1979, at 5 (1952), and H.R. Rep. No. 82-1923, at 6 (1952)).

The plain language of § 101 authorizes patents for a "new" "composition of matter." Here, there appears to be no reasonable dispute that the genetically engineered host cell is both "new" and a "composition of matter." Of course, over the years, courts have created judicial exceptions, but none of the judicial exceptions ever contemplated a recombinant cell made in a laboratory using revolutionary technology discovered in the 1970s and barely contemplated, if at all, by Congress in 1952. Appellants' opening brief shows that there is no dispute about the claimed bacterial host cell being a human-made construct, as it is engineered to contain a non-naturally occurring recombinant nucleic acid molecule that

contains the two specific DNA sequences, *i.e.*, an AAV sequence and a heterologous non-AAV sequence.

B. The District Court's Decision Flies in the Face of *Chakrabarty* and Decades of Precedent

Beyond the statute, it is not possible to reconcile the district court's holding with the Supreme Court's ruling in *Chakrabarty*. This again is another independent basis for reversing and holding that summary judgment should have been granted in favor of Appellants.

In *Chakrabarty*, the invention was a genetically engineered bacterium that was created—through human intervention—to degrade crude oil. 447 U.S. at 305. To make the engineered bacterium, the scientists transferred naturally occurring DNA plasmids, which encoded for proteins that could degrade hydrocarbons, the *Pseudomonas* bacterium. *Id.* By doing so, the scientists created a new bacterium which, absent human intervention, could not express the proteins that degrade crude oil. *Id.* at 305 n.1. The novel, genetically engineered bacterium was made of biological components that separately existed in nature but were combined in a way that created a "new" "composition of matter" and having characteristics that were "possessed by no naturally occurring bacteria." *Id.* at 305.

As should be evident, the invention at issue in this case is conceptually no different than what the Supreme Court held as patent eligible in *Chakrabarty*. Both inventions were directed to genetically engineered organisms, made possible only through human innovation and intervention. Both inventions do not exist in nature. Both inventions create engineered cells that have physical characteristics that are different than the naturally occurring cells.

Moreover, subsequent cases have not changed the impact of *Chakrabarty*. Start with *Myriad*. While the Supreme Court reiterated the "markedly different" analysis, the key was that the claimed BRCA genes in that case occurred in nature. 569 U.S. at 590–91. The Court was emphatic: "Myriad did not create anything." *Id.* at 591.

But here, the inventors did create something—and it was something that never existed before their creative efforts. They engineered a novel host cell with a unique plasmid DNA that expresses specific proteins. That distinction alone shows how the Supreme Court's concern about monopolizing "the information-transmitting quality of the DNA" is not applicable here and does not alter how *Chakrabarty* controls the outcome.

Importantly, the Supreme Court in *Myriad* stated that it was "important to note what is *not* implicated" by the decision there. 569 U.S. at 595 (emphasis in original). The Court recognized that it was not "consider[ing] the patentability of DNA in which the order of the naturally occurring nucleotides has been altered." *Id.* at 596. That issue is implicated here, however, as it was in *Chakrabarty*. The genetically engineered organisms exist only because there is a novel combination of DNA sequences that does not exist in nature. Indeed, as the Court recognized, "[s]cientific alteration of the genetic code presents a different inquiry." *Id.* Scientific alteration of the genetic code is at the root of genetic engineering. While that same phrasing was not used in *Chakrabarty*, that case necessarily understood that genetically engineered organisms—created by the manipulation and scientific alteration of the genetic code—are patent-eligible inventions under 35 U.S.C. § 101. The same sound reasoning should be applied in the present case to reach the only rational outcome.

III. The District Court's Confusion Highlights The Need For Patent Reform

In one sense, the district court's decision is utterly shocking. Who would have imagined, just a handful of years ago, that federal courts

would use § 101 to regularly invalidate patents for groundbreaking, gene-based technologies? Indeed, the type of innovation here was not even remotely possible when Congress passed the 1952 Patent Act, and only through human innovation have we reached the stage where scientists can create extremely useful genetically modified organisms.

The district court's erroneous decision appears to be a manifestation of the confusion that imbues current patent-eligibility jurisprudence. The continuing confusion is all the more reason why Congress must act to improve the law by passing the Patent Eligibility Restoration Act ("PERA"), S. 2140, 118th Cong. (2023).[9] While new legislation is unnecessary to correct the error in this appeal, legislation to improve § 101 will lessen the likelihood of additional aberrant decisions such as the one at issue here.

[9] https://www.congress.gov/bill/118th-congress/senate-bill/2140.

A. Patent-Eligibility Law Remains a Mess

"The law of patentable subject matter is a mess."[10] That assessment was widely circulated after it was made to Congress almost five years ago. Unfortunately, the assessment remains true today.

Members of this Court have highlighted the confusion in patent-eligibility law. Chief Judge Moore, for instance, observed that the "blended 101/112 analysis" applied in one case "expands § 101, converts factual issues into legal ones and is certain to cause confusion for future cases." *Am. Axle & Mfg., Inc. v. Neapco Holdings, LLC*, 967 F.3d 1285, 1305 (Fed. Cir. 2020) (Moore, J., dissenting); *see also Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1337 (Fed. Cir. 2019) (Hughes, J., concurring) ("I, for one, would welcome further explication of eligibility standards in the area of diagnostics patents.").

Despite this Court's efforts to apply Supreme Court precedent, innovators are left with seemingly inconsistent outcomes, with some patents covering innovative diagnostic methods upheld while other very similar inventions are deemed patent ineligible. *See, e.g.*, *Illumina, Inc.*

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[10] Mark A. Lemley, *Patentable Subject Matter* Reform Hearings Before the Senate Judiciary Committee, at 1 (June 4, 2019), https://www.judiciary.senate.gov/imo/media/doc/Lemley%20Testimony.pdf.

v. Ariosa Diagnostics, Inc., 952 F.3d 1367, *opinion modified by* 967 F.3d 1319 (Fed. Cir. 2020); *Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co. KG*, 933 F.3d 1302, 1319–20 (Fed. Cir. 2019) (invalidating claims for detecting hereditary nasal parakeratosis in Labrador retrievers); *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363, 1381 (Fed. Cir. 2018) (invalidating a patent directed to novel methods for detecting the pathogenic bacterium *Mycobacterium tuberculosis*); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1052 (Fed. Cir. 2016) (holding, as patent eligible, a method of producing a preparation of multi-cryo-preserved hepatocytes).

B. Congress Should Fix the Law by Passing the Patent Eligibility Restoration Act ("PERA")

Here, the district court's erroneous outcome appears to be a product of existing confusion in patent-eligibility law. As noted above, this Court can and should rectify that error by correctly applying precedent. It need do no more.

At this time, it is worth acknowledging that much of the responsibility for fixing the confusion in patent-eligibility law lies not with this Court but with Congress. It has been fourteen years since the Supreme Court started its campaign to rework patent-eligibility law. *See Bilski v.*

Kappos, 561 U.S. 593 (2010). It has been far from successful with its follow-on decisions in *Alice Corp. Pty. Ltd. v. CLS Bank International*, 573 U.S. 208 (2014), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012). Due to the lack of clear guidance from the Supreme Court, this Court has had to wrestle with the reimagined confines of patent-eligible subject matter. Despite pleas from this Court, the Supreme Court has declined numerous opportunities to make the necessary corrections.

If patent-eligibility law is not rationalized, the consequences will continue to worsen for the U.S. innovation community. While patents for lifesaving technologies are struck down in the United States under vague "judicial exceptions," the same or very similar inventions are deemed worthy of patent protection in Europe and Asia. Moreover, the United States needs to take concrete steps to improve its leadership on the global innovation stage, lest the nation fall far behind advancing competitors.

That leaves Congress to improve the situation. Current pending legislation, specifically the PERA, is the best current solution for improving the law and providing clearer boundaries for this Court to apply. Introduced by Senators Tillis and Coons, the proposed legislation would

simplify the patent-eligibility analysis by codifying specific, defined exceptions to patent-eligible subject matter and would thus minimize aberrant decisions, such as the one at issue in this case.

The courts cannot, of course, enact legislation. Even so, a court is free to express its view that legislation is needed to improve the quality of its judicial decisionmaking. The Supreme Court has done so on several occasions. *E.g.*, *Sinclair Refining Co. v. Atkinson*, 370 U.S. 195, 214 (1962) ("The question of what change, if any, should be made in the existing law is one of legislative policy properly within the exclusive domain of Congress—it is a question for lawmakers, not law interpreters."). Here, the Supreme Court's repeated cert-petition declinations are, in effect, an invitation to this Court to emphasize the need for legislative action to improve the law. *See, e.g.*, *In re Thorpe*, 777 F.2d 695, 698 (Fed. Cir. 1985) ("It is the province of Congress to make changes in law based on public policy.").

IV. Conclusion

For the foregoing reasons, *Amicus* respectfully submits that the Court should reverse the grant of summary judgment that held the claims to be patent ineligible. The Court should rule that, as a matter of

law, the claimed genetically modified cells are patent eligible. The suggested outcome will then allow the parties to litigate whether the claimed invention satisfies the statutory requirements of patentability under 35 U.S.C. §§ 102, 103, and 112.

Date: May 17, 2024

Respectfully submitted,

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July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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