No. 12-398

In The
Supreme Court of the United States

ASSOCIATION FOR
MOLECULAR PATHOLOGY, ET AL.,

Petitioners,

vs.

MYRIAD GENETICS, INC., ET AL.,

Respondents.

**On Writ Of Certiorari To The
United States Court Of Appeals
For The Federal Circuit**

BRIEF OF *AMICUS CURIAE* NATIONAL VENTURE CAPITAL ASSOCIATION IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*[1]

The National Venture Capital Association (NVCA), with more than 400 members, is the venture community's preeminent trade association, advocating for policies that encourage innovation and reward long-term investment. NVCA's mission is to foster greater understanding of the importance of venture capital to the U.S. economy and support entrepreneurial activity and innovation. Venture capitalists are committed to funding America's most cutting-edge entrepreneurs, working closely with them to transform breakthrough ideas into emerging growth companies that put innovation in the hands of the public and drive U.S. job creation and economic growth. According to a 2011 IHS Global Insight study, venture-backed companies accounted for nearly 12 million jobs and $3.1 trillion in revenue in the United States in 2010.

NVCA and its members have an interest in preserving the patent rights that have created and continue to sustain the biotechnology industry, bringing life-changing technologies to market and spawning new high-growth companies.

[1] No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae* or their counsel made a monetary contribution intended to fund its preparation or submission. The parties have consented to the filing of this brief.

SUMMARY OF ARGUMENT

The venture community is the primary founder and funder of biotechnology in the United States, an industry which, year after year, provides hundreds of thousands of jobs, generates hundreds of billions of dollars in revenue, and makes available to the general public countless life-changing and life-saving innovations. *See* Ernst & Young, *Beyond Borders, Global Biotechnology Report* 27, 30 (2012) ("*Beyond Borders*"); Global Insight, *Venture Impact, The Economic Importance of Venture Capital-Backed Companies to the U.S. Economy* 9 (2011) ("*Venture Impact*"). Both Genentech and Amgen – companies that gave birth to modern biotechnology – were funded by venture capitalists. And today, venture capital firms supply nearly all of the capital for early-stage biotechnology companies.

Unlike in other technology sectors, start-up biotechnology companies are faced with long development timelines, unpredictable science, and uncertain industry adoption. In particular, the industry faces significant (with respect to both time and cost) regulatory hurdles. Venture capitalists are able to fund these not-yet-profitable emerging companies through the high-risk and high-cost development process because patent protection in the underlying technology makes possible potentially large rewards if a product can be brought to market. *See* Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, A Report by the Federal Trade Commission*, Chp. 3, p. 1 (2003)

("FTC Report") ("Biotech representatives emphasized that patent protection is critical to attract the capital necessary to fund this high-risk investment."). Indeed, it was this Court's confirmation of Congress' broad view on patent eligibility as articulated in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), that opened the door to patents covering isolated nucleic acids and the founding of modern biotechnology. FTC Report at Chp. 3, pp. 17-18. Soon after the *Chakrabarty* ruling, patents covering DNA encoding human growth hormone and erythropoietin issued, enabling venture capital investment in the early founders of modern biotechnology, Genentech and Amgen.

Since the success of Genentech and Amgen, venture capitalists have relied on the continuing issuance of these patents by the PTO, the PTO's consideration and confirmation of the patent eligibility of such inventions in its practice guidelines, and the enforcement of these patents by the courts to continue funding. Removing patent eligibility for isolated nucleic acid patents threatens an industry built on thirty years of precedent and industry practice. It not only forfeits the billions of dollars currently invested and hundreds of thousands of jobs created with the understanding that returns would be secured by nucleic acid patents, but also removes incentives for future investment in important new nucleic-acid based technologies, such as molecular diagnostics, gene therapies, agricultural food production, and alternative energy sources.

This Court has warned that "courts must be cautious before adopting changes that disrupt the settled expectations of the invention community." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002), *citing Warner-Jenkinson v. Hilton Davis Chem. Co.*, 520 U.S. 17, 18 (1997). The biotechnology industry's settled expectations regarding the patent eligibility of isolated nucleic acid is the foundation of the entire industry and continues to facilitate innovation and economic growth. Accordingly, this Court should confirm that isolated nucleic acids are patent eligible and affirm the Federal Circuit's ruling in favor of Respondents.

ARGUMENT

I. THIS COURT'S PRECEDENT CAUTIONS AGAINST DISTURBING SETTLED EXPECTATIONS.

In the more than thirty years following this Court's recognition that § 101's legislative history intended "anything under the sun that is made by man" to be patent-eligible, both the legal and business community have relied on the understanding that inventions directed to isolated nucleic acids are patent-eligible under § 101. *See Chakrabarty*, 447 U.S. at 309 (citations omitted); *see also id.* at 316 (recognizing that "Congress employed broad general language in drafting § 101").

According to a 2003 Report by the Federal Trade Commission, the description of patent-eligible subject matter articulated in *Chakrabarty* "conveyed a broad sense of the potential scope of patents and, in particular provided a significant boost to the biotech industry." FTC Report at Chp. 1, p. 21 ("participants from the biotech industry generally credited the *Chakrabarty* decision as the beginning of their industry, without which genetic engineering would not have made nearly as much progress"); *see also id.* at Chp. 3, p.17 (reporting that participants stated that "*Chakrabarty* spurred significant growth in the biotech industry").

Consequently, in the thirty years since the *Chakrabarty* decision, the United States Patent and Trademark Office has granted tens of thousands of patents covering nucleic acids. *See* National Research Council of the National Academies, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* 101-02 (Stephen A. Merrill & Anne-Marie Mazza, 2006) ("*Reaping the Benefits*") ("From 1971 to 2006, approximately 33,000 issued nucleic acid patents have been identified."). Between 1995 and 2005 alone, over 6000 nucleic acid patents were issued, with an additional 7000 applications pending. *Id*. at 106. Over time, the PTO and courts have confirmed the validity of isolated DNA patents. *See e.g.* 66 Fed. Reg. 1092, 1093 (PTO Utility Examination Guidelines finding patenting of genes proper); *Amgen v. Chugai*, 927 F.2d 1200 (Fed. Cir. 1991) (first appellate decision that, in part, finds

valid a claim to "purified and isolated DNA sequence . . . encoding human [protein]").

Most of these inventions are owned by private companies, many of which depend on these patents and patent applications to secure the capital necessary to develop and commercialize the underlying technology. *Reaping the Benefits* at 115; *see also e.g.* Federal Trade Commission, *Emerging Health Care Issues: Follow-on Biologic Drug Competition* v (2009) ("Patent protection enables biotechnology firms to increase their expected profits from investments in R&D, thus fostering innovation that would not occur without patents' exclusionary rights."); President's Council of Advisors on Science and Technology, *Priorities for Personalized Medicine* 21 (2008) ("PCAST *Priorities*") ("The ability to obtain strong intellectual property protection through patents has been, and will continue to be, essential for pharmaceutical and biotechnology companies to make the large, high-risk R&D investments required to develop novel medical products"). With this promise of patent protection, venture capitalists invested more than $35 billion in biotechnology between 2002 and 2011, with more than $4 billion invested in 2011 alone. *See Beyond Borders* at 44.

Reinterpreting § 101 now to exclude isolated nucleic acids from patent protection would disturb the investments and expectations established over more than three decades of practice. Nucleic acid patents gave rise to the modern biotechnology industry and continue to enable investment in emerging

companies, bringing medical, agricultural and industrial innovations to market and promoting economic growth. This Court has "more than once cautioned that courts 'should not read into the patent laws limitations and conditions which the legislature has not expressed.'" *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3128, 3228 (2010), *quoting Diamond v. Diehr*, 450 U.S. 175, 182 (1981); *see also Association for Molecular Pathology v. United States Patent and Trademark Office*, 653 F.3d 1329, 1374 (Fed. Cir. 2011) (Moore concurring in part) ("the judiciary is ill-suited to determine whether the claims at issue promote or inhibit science and useful arts in all but the clearest cases").

This warning is particularly noteworthy in the case of isolated nucleic acids, where Congress – though presented with the opportunity to do so – has declined to express any limitations on patent eligibility. For example, in 1993, the Life Patenting Moratorium Act was introduced in the Senate, proposing a two-year moratorium on the patenting of any "human tissue, fluid, cell, gene or gene sequence (genetically engineered or otherwise)." *See* S. 387, 103d Cong., 1st Sess. (1993). In 2007, the Genomic Research and Accessibility Act introduced in the House, contained a provision expressly precluding patenting of "a nucleotide sequence, or its functions or correlations." *See* H.R. 977, 110th Cong., 1st Sess. (2007). Both bills died in committee. Finally, in the recent enactment of the America Invents Act, the first major patent reform bill in fifty years, Congress instituted no limits on the

patent eligibility of genes or other isolated nucleic acids. Instead, the legislative history reveals that Congress was aware that the Patent Office has already issued gene patents and was comfortable with legislation that would not affect that practice. *See* 157 Cong. Rec. E1177-04 (resubmitting testimony in connection with the AIA that stated "the U.S. Patent Office has already issued patents on genes . . . , but it has not issued patents on claims directed to human organisms, including human embryos and fetuses. My amendment would not affect the former, but would simply affirm the latter").

As this Court has recognized, "we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary." *Mayo Collaborative Serv. v. Prometheus Labs., Inc.*, 566 U.S. ___, 132 S. Ct. 1289, 1305 (2012); *see also Bilski*, 130 S. Ct. at 3229 (warning against "adopting categorical rules that might have wide-ranging and unforeseen impacts"). Not only have the rules here been long established, they have been relied upon to foster an industry that plays a significant role in furthering U.S. economic growth.

II. BIOTECHNOLOGY WOULD NOT EXIST WITHOUT PATENTS.

A. Biotechnology Is Marked By High Development Costs

Biotechnology covers a diverse collection of technologies, each of which capitalizes on the attributes of biological materials. *See* Biotechnology Industry Organization, *Guide to Biotechnology* 1 (2008) ("BIO Guide"). Thus, biotechnology reaches across many sectors, revolutionizing health care (*e.g.*, molecular diagnostics, biological therapeutics, vaccines, and pharmaceuticals), improving agriculture, and developing alternative energy sources. *See generally id.* at 32-69.

Regardless of the application, biotechnology products often take more than ten years and hundreds of millions of dollars to develop and bring to market. *Id*. at 77. Research and development is expensive and challenging. The underlying laboratory science can be laborious and unpredictable. Many sectors are subject to significant regulatory hurdles. *See e.g. id.* at 39-40 and 44 (describing regulatory process for therapeutics and agriculture). Even after securing regulatory approval, market success still requires industry adoption.

For example, bringing a molecular diagnostic to market requires laborious work with respect to the underlying science, including ensuring sufficient sample sizes, quality control in the underlying DNA sampling, a rigorous statistical approach to analyzing

data, and a consistent standard across the industry. PCAST *Priorities* at 29-30. Moreover, the industry faces significant obstacles when navigating the regulatory environment. In particular, molecular diagnostics are subject to long, expensive clinical trials. In addition, the current regulatory system is not designed to accommodate new complex genomics-based diagnostics and for that reason can be even more costly to navigate. *Id*. at 41. And the regulatory requirements continue to increase year by year. There is also the practical necessity of convincing insurance companies, Medicare, and Medicaid to pay for these new tests, which requires robust evidence supporting the safety and efficacy of products. *Id*. at 45-48.

Development of new therapeutics is similarly mired by the cost of basic research, clinical trials, and post-approval testing. It is estimated that bringing a single biotechnology-related therapeutic to market takes 15 years and costs over $1.2 billion. *See* Henry Grabowski, *Follow-on Biologics, Data Exclusivity and the Balance Between Innovation and Competition*, 7 Nature Reviews Drug Discovery 479, 482 (2008) ("Grabowski"); BIO Guide at 38 ("It typically takes 10 to 15 years and an average of more than $800 million (including the cost of failures) to develop a new therapy."); *see also* PhRMA, *Key Industry and PhRMA Facts*, available at http://www.phrma.org/news-media/related-resources/key-industry-factsabout-phrma. Only an estimated 30 percent of biological therapeutics that make it as far as human trials succeed. Grabowski at 481.

B. Patents Enable Venture Capital Investment in Biotechnology

Most of the companies driving these new biotechnological innovations are small, having less than fifty employees. Without a significant source of capital, even when the technology is sound, these companies would run out of money before a product could ever be brought to market. BIO Guide at 77.

Thus, these companies simply would not exist without venture capital, often the only available source of funding for high-risk start-ups. *See* NVCA, *Patient Capital: How Venture Capital Investment Drives Revolutionary Medical Innovation* 7 (2007) ("*Patient Capital*") ("Because their capital needs are so large and their path to market so long and risky, it is difficult for life sciences startups to access bank financing or other more traditional sources of capital."). Indeed, venture capital funds almost all emerging biotechnology companies. *See* Hearing Before the Subcommittee on Courts and Competition Policy of the Committee on the Judiciary House of Representatives, *Biologics and Biosimilars: Balancing Incentives for Innovation* 182, 107th Cong., 1st Sess., Serial No. 111-73 (July 14, 2009) ("*Biologics* Hearing") (NVCA testimony that venture capital firms "supply nearly all of the capital for early-stage biotechnology companies"); *Patient Capital* at 3 ("Experts agree that virtually the entire biotechnology industry . . . would not exist without the support of the venture capital industry.").

To secure this much-needed venture capital investment, a company must have strong intellectual property in the form of patents. BIO Guide at 77 (noting that patents are "often the most important assets a biotech company has"); *Patient Capital* at 12 ("No other industry is as dependent on developing and protecting intellectual property as the life sciences industry."). In fact, the biotechnology industry would not exist but for patents. FTC Report at Chp. 3, pp. 1, 17-18 (reporting that "[b]iotechnology companies overwhelmingly underscored the importance of patents for attracting venture capital"). As reported by the Federal Trade Commission:

> Biotechnology innovation is heavily dependent on the patent rights that have been available for biotechnology inventions since 1980. Patents help firms to recover high, fixed R&D costs and are particularly useful in enabling biotechnology companies, which are generally small in size, to attract capital investment and to contract with other firms for commercial development of their inventions. This capital is critical for ongoing R&D, because product commercialization in the biotechnology industry is particularly time-consuming and expensive.

Id. at Chp. 3, p. 29. Patents provide the incentive for venture capitalists to invest in the "incredibly risky, illiquid, and long-term investments" required by biotechnology companies, over half of which fail. *Biologics* Hearing at 182. They are needed to "produce a return that is much higher than you can get from less

risky investments" by "provid[ing] a period of exclusivity with respect to the manufacture, use, or sale of the product." *Id*.; *Reaping the Benefits* at 20; *see also* Claude Barfield, et al., *Biotechnology and the Patent System* 11 (2007) ("Investors believe that in order for the biotechnology sector to succeed, it is critical that biotechnology firms be able to obtain and enforce strong patents.").

Thus, strong patent protection, including for isolated nucleic acids, is imperative to secure the investment that drives continued biotechnological innovation.

III. ISOLATED NUCLEIC ACID PATENTS ARE THE FOUNDATION OF MODERN BIOTECHNOLOGY.

The importance of patents, and isolated nucleic acid patents in particular, to venture capital financing and the resulting realization of new revolutionary technologies is not merely theoretical. In fact, it was nucleic acid technology that enabled venture capital investment in Genentech, the company often credited with the birth of the biotechnology industry. *See e.g.* BIO Guide at 2 (crediting emergence of biotechnology on development of recombinant DNA technology by co-founder of Genentech); *see generally* Cynthia Robbins-Roth, *From Alchemy to IPO: The Business of Biotechnology* (2000) ("*Alchemy*").

Genentech was founded in 1976 based on recombinant DNA technology developed by scientists at

Stanford University and the University of California, San Francisco. *Alchemy* at 14. The scientists applied for patents covering this new DNA-based technology. *Id*. at 15. Based on this technology, the company was founded with the help of the venture capital firm Kleiner, Perkins, Caufield & Byers. *Id*. Initial funding lasted nine months, during which time Genentech worked on its "proof of concept," cloning genes for insulin and human growth hormone out of Kleiner Perkins' offices. *Id*. at 16. The next year, Kleiner Perkins invested another round and Genentech secured additional financing by selling rights to its technology. *Id*. at 25. It is estimated that isolation of the human insulin gene – rights to which were sold to Eli Lilly – took over $100 million and 1000 human years of labor. By 1979, Genentech expanded its technology and filed a patent application covering its technique for cloning human growth hormone. *See* Ser. No. 55,126, U.S. Patent No. 4,342,832. This patent application eventually gave rise to a patent claiming "a DNA molecule consisting of DNA encoding . . . human growth hormone." U.S. Patent No. 4,898,830.

Armed with its patent applications and the proof of concept made possible through Kleiner Perkin's investment, Genentech went public in October 1980, raising over $35 million. *Alchemy* at 20. In 1985, Genentech marketed its first drug, Protropin®, secured by its human growth hormone DNA patent. *Id*. at 29; *see also* http://www.omnilegalgroup.com/GeneWars.pdf at 17 n.xxxix (noting that HGH was

marketed as Protropin® and is covered by U.S. Patent No. 4,898,830). By 1998, revenues for Protropin® reached $214 million. *Alchemy* at 28.

Amgen is another company that experienced a similar success story. Formed in 1980 by a group of scientists and investors, Amgen secured $19 million in financing from venture capital firms and two major corporations. *Alchemy* at 34. By the mid-1980s Amgen had five genetically engineered drugs undergoing testing but its work with erythropoietin was most promising. Erythropoietin (EPO) is a hormone that promotes red blood cell production. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1203 (Fed. Cir. 1991). In a race with six other companies to isolate the EPO gene sequence, by 1984, Amgen had applied for a patent claiming "an isolated and purified DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin." Ser. No. 675,298, U.S. Patent No. 4,703,008; *see Alchemy* at 39. Following the issuance of its EPO patent in 1987, Amgen received FDA approval for its Epogen product in 1989 and has since successfully enforced its patent against competitors to secure market exclusivity. *Amgen*, 927 F.3d at 1219 (affirming validity of EPO DNA sequence claims and finding of infringement). To date, Epogen remains one of Amgen's leading products. Facilitating venture investment in these emerging biotechnology companies through patents covering isolated nucleic acids not only ensures that the public will enjoy the benefits of new breakthrough innovations, it brings about far-reaching downstream economic benefits as well.

Genentech and Amgen's success, secured by patents covering isolated nucleic acids, spurred the growth of an industry. Biotechnology is now an industry with over $58 billion in annual revenue. *Beyond Borders* at 27. In 2010, venture-backed biotechnology companies realized $161 million in revenue and accounted for 400,000 jobs. *Venture Impact* at 9.

While venture capital investments equal less than 0.2 percent of the US GDP, annually, VC-backed companies have generated revenue equal to 21 percent of the US GDP. *Venture Impact* at 2. Venture-backed companies constituted 11 percent of private sector jobs in 2010. *Id*. at 3. The biopharmaceutical industry, for instance, has an enormous ripple effect throughout the economy. The Milken Institute projects that for every job within biopharmaceuticals, an additional 6.7 jobs are created in other sectors of the economy. *Patient Capital* at 8, *citing* Milken Institute, *Biopharmaceutical Industry Contributions to State and U.S. Economies* (2004).

A reduction of these jobs and the revenues generated by eliminating venture-backed companies will have significant unintended consequences on the economy. Indeed, venture-backed companies have been sustaining the economy, outperforming the total overall economy in 2009-2010. *Venture Impact* at 2. Where overall revenues decreased 1.5 percent, venture-backed revenue grew 1.6 percent, totaling $3.1 trillion in 2010 (10% of total U.S. sales). *Id*. at 3.

Thus, the current system which has been relied upon for over thirty years has supported steady economic growth and support for new technologies and emerging industries.

IV. THE BIOTECHNOLOGY INDUSTRY CONTINUES TO RELY ON PATENTS COVERING ISOLATED NUCLEIC ACIDS.

The industry's reliance on isolated nucleic acid patents is not just historical. Nucleic acid patents continue to play an important role in bringing biotechnological advancements to market.

Patents on isolated DNA molecules continue to support investment in new revolutionary technologies.

4s3 Bioscience is a venture-backed bio-therapeutics company developing therapies for genetic neuromuscular diseases. Founded in 2007, 4s3 Bioscience has two pending patent applications with claims directed to a "nucleic acid construct containing a nucleotide sequence that encodes a MBNL [MTMI] polypeptide." *See* U.S. Patent Pub. Nos. 2010/0111977 and 2012/0213760. With these patent applications, 4s3 Bioscience secured $20 million in Series A financing in March 2012 to fund further development of antibody technology that provides targeted and active delivery of proteins, enzymes, and other molecules to skeletal muscle. *See* http://www.alopexx.com/press_release/4s3-bioscience-inc-secures-20m-in-series-a-financing/.

As seen with the 4s3 Bioscience technology, nucleic acid patents are important to the continued development of protein therapeutics and the emerging field of gene therapy. Gene therapy uses DNA or related nucleic acid molecules to treat diseases by supplying a patient with a replacement, non-defective gene. Development of this technology has the potential to save lives through the treatment of cancers and immunodeficiency diseases. *See* BIO Guide at 34.

Denying patent protection for human DNA also puts patents covering isolated nucleic acids of other organisms at risk. Patent protection for bacterial or plant nucleic acids has significant impact on the development of agricultural, industrial, and environmental products. Funding for continued research and development into the genomes of bacteria and algae, for example, has the potential to lead to great innovation in alternative energies and potential sources for biofuels. For example, cellulosic ethanol technologies, which can process non-food plant materials (*e.g.*, grass, wood, and crop waste) into ethanol, rely heavily on cellulose and hemicellulase genes isolated from microorganisms that break down the materials. The many issued patents that are directed to isolated DNA coding for these cellulases and hemicellulases have been critical in driving rapid innovation in this industry. And patents for isolated plant DNA can improve agricultural practices, decrease the cost of food, and help address the global food supply. *See* BIO Guide at 53.

The potential applications of nucleic acid technology, involving human DNA as well as DNA of other organisms, is limitless. Stifling such innovation into new and unexplored territories will lead to unforeseen and undesired consequences. Biotechnology has historically benefitted and brought life-changing innovation based upon the understanding that isolated nucleic acids are patent-eligible. Changing that practice now will halt the type of progress and advancements that the industry and society has experienced over the last thirty years.

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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