No. 12-398

IN THE

Supreme Court of the United States

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, *et al.*,

Petitioners,

v.

MYRIAD GENERICS, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICI CURIAE* ANIMAL HEALTH INSTITUTE AND MERIAL LIMITED IN SUPPORT OF RESPONDENTS

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INTERESTS OF *AMICI CURIAE*[1]

Amicus Curiae Animal Health Institute ("AHI") is a trade association representing companies in the animal health field. AHI is made up of 23 member companies[2] who supply farmers, veterinarians, and pet owners with a comprehensive range of pharmaceuticals, vaccines, and diagnostics developed and produced using both traditional technologies and modern biotechnology. The animal health industry has a multi-billion dollar impact on the U.S. economy annually, and its reach extends to much broader industries and concerns. Animal health inventions developed by AHI members—such as vaccines for cancer, foot and mouth disease, West Nile virus, avian flu, E. coli, and the H1N1 virus—not only improve the health, welfare, and productivity of animals, but also ensure food

1. Pursuant to Supreme Court Rule 37.6, counsel for *Amici Curiae* represents that none of the parties or their counsel authored this brief in whole or in part and that no person or entity other than *Amici Curiae* made a monetary contribution to its preparation or submission. Petitioners have lodged a blanket consent to the filing of *amicus* briefs, and written consent by Respondents to the filing of this brief has been lodged with the Clerk of Court.

2. The licensed and affiliate members of AHI are: Abbott Animal Health; Bayer Healthcare LLC, Animal Health Division; Bioniche Animal Health USA; Boehringer-Ingelheim Vetmedica, Inc.; Colorado Serum Company; ECO Animal Health; Elanco Animal Health; Merck Animal Health; Merial Limited; MVP Laboratories, Inc.; Novartis Animal Health US, Inc.; Phibro Animal Health; Virbac Corporation; Zoetis; AlcheraBio LLC; Benchmark Biolabs, Inc.; Animal Clinical Investigation; Aratana Therapeutics, Inc.; Biotechnical Services, Inc.; Mars Veterinary; MPI Research; Nestle Purina PetCare Company; and VetPharm, Inc.

safety, protect human health, support a competitive and sustainable agricultural sector, and help to preserve the environment.

AHI members annually invest hundreds of millions, if not billions, of dollars on the innovations, research, and science necessary for advances in pharmaceuticals, biologics, and pesticides for animals. Many of the products that AHI's members are developing stem from discoveries of creating isolated deoxyribonucleic acid ("DNA") molecules associated with animal disease, and AHI's members have applied for and received numerous patents for inventions involving isolated DNA molecules. Thus, they have a significant interest in the patentability of created DNA molecules.

Amicus Curiae Merial Limited ("Merial"), one of AHI's member companies, is a world-leading animal health company with its North American headquarters in Duluth, Georgia. Merial's world-wide 2010 sales were over $2.6 billion. Merial provides a comprehensive range of pharmaceutical products, vaccines, and diagnostic products to enhance the health, well-being, and performance of livestock, pets, and wildlife. Merial works with governments around the world to contain and manage various animal diseases for the benefit of both animals and humans.

Merial has a proven track record of discovering and developing cutting edge animal health products, and the company has launched new products every year since its inception in 1997. To that end, Merial makes significant investments in research and development. Merial develops and manufactures pharmaceuticals and vaccines

with the highest level of quality, safety, and efficacy through a network of nine research and development centers and fifteen manufacturing sites. Merial employs approximately 5,700 people worldwide. More than half of Merial's research and development group is stationed in the United States, and Merial invests over $100 million annually in research and development in the United States alone.

Like other AHI members, Merial has applied for and received numerous patents for inventions involving isolated DNA molecules. Merial has a particular interest in the issues involved in this appeal because of a recent decision by the United States Court of Appeals for the Federal Circuit involving one of Merial's patents. *See Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282 (Fed. Cir. 2010). In the *Intervet* case, Judge Dyk, in an opinion concurring in part and dissenting in part, questioned whether one of the patent's claims covering an isolated DNA molecule constituted patentable subject matter under 35 U.S.C. § 101. *See Id.* at 1292 (Dyk, J., concurring in part and dissenting in part).

SUMMARY OF THE ARGUMENT

The question presented, "[a]re human genes patentable," is answered, generally speaking, in the negative. Genetic material, as it exists in the human body, does not constitute patentable subject matter. The question presented by petitioners was carefully crafted to evoke an emotional response—in particular, to frame the issue as one concerning whether the natural makeup of humans, *i.e.* their DNA, can be owned by someone else. Patents to human genes, however, are not the same as

patents to isolated (*i.e.* created) DNA molecules. Thus, the more important, narrower question is whether isolated genetic molecules such as those covered by the challenged patent claims—which do not occur in nature, which are not found in the body of a human or animal, and which require substantial transformation from the genetic material indigenous to organisms—constitute patentable subject matter under 35 U.S.C. § 101. The answer to that more precise question is "yes."

When it comes to patent eligibility, a DNA molecule—although perhaps more complex—should be treated no differently than other molecules, for example polymers (*see, e.g.,* C.A. App. A3707 at ¶ 25). More than anything, this case is about chemicals and, in particular, whether a human-made molecule, which is not found in nature and which has markedly different characteristics from any substance found in nature, but which is derived from a larger, naturally occurring molecule, is eligible for patenting. Under the current patent system, as established by Congress, the answer, again, is "yes."

The consequences of ruling against the patentability of human-created genetic molecules are real and vast.[3] Such a decision would (i) undermine innovation and inhibit investment in all new genetic technologies, since the

3. Petitioner and other *Amici Curiae* that submitted briefs in support of the Petitioner suggest that this Court could craft a narrow ruling that impacts only isolated DNA molecules with respect to humans. There appears to be no legal basis for limiting a "narrow" order to the genetic materials of humans only (as opposed to, for example, the isolated genetic molecules of animals and other organisms), and therefore this Court's opinion will affect a broad swath of industries.

incentives provided by the patent system would no longer exist and (ii) likely create dissonance between the patent laws of the United States and those of the rest of the world.

First, the patent laws of the United States are, of course, designed to reward innovators by giving them an exclusive right of limited duration in which to practice their invention(s). Petitioners' Brief focuses primarily on the misplaced notion that this system is somehow unjust, at the expense of fully addressing whether isolated molecules constitute patentable subject matter. It appears that Petitioners' main grievance is not that created genetic molecules purportedly constitute unpatentable subject matter, but instead that the United States' patent laws are working as intended with the result that Petitioners are excluded from practicing someone else's invention. Petitioners have it backwards. If the statutory incentives for invention with regard to created genetic molecules are eradicated, innovation in that field will cease or, at the very least, be substantially diminished. Thus, Petitioners would be left in the same position they are now, unable to practice an invention (since it would not exist), yet society as a whole would suffer since, again, the invention would not exist. This situation would carry forward, and new DNA-based inventions like the claimed isolated DNA molecules at issue would never be developed.

This same *quid pro quo* of patent law also applies to the animal health industry. The ability of AHI's members to bring DNA-based animal health products to market depends heavily on their ability to recoup the substantial investments necessary to discover, develop, obtain regulatory approval for, and commercialize inventions relating to human-created genetic material. To get back

these investments, Merial and other AHI members rely on the ability to patent their created DNA molecule discoveries and on the limited period of exclusivity that comes with such patents. If created DNA molecules were not patentable, this important incentive would disappear.

Second, there are benefits to global patent law harmonization that would be undermined by a ruling that calls into question the validity of DNA-based inventions. In addition to the numerous patents involving isolated DNA molecules issued by the United States Patent and Trademark Office ("PTO") and upheld by the Federal Circuit, the European Patent Office ("EPO") allows for the patentability of biological material, such as DNA, provided the material is isolated from its natural environment or produced by means of a technical process. With respect to patents related to those at issue here, the EPO has praised European counterparts to the challenged patents for their innovation. In addition, a recent decision from the Federal Court of Australia held that a patent related to the ones at issue here, covering isolated genetic molecules, is patentable provided that the other requirements for patentability are met. Harmonization of what constitutes patentable subject matter is particularly important to global companies, like Merial, who usually patent related inventions in numerous countries.

Further, the PTO has approved thousands of patents involving isolated DNA molecules and, when these patents have been challenged, the Federal Circuit has upheld them. In so doing, the PTO and Federal Circuit have been correct as a matter of law because created DNA molecules (i) fit squarely within the definition of "manufacture[s]" and "compositions of matter," or at the

very least "new and useful improvements thereof," and (ii) are chains of chemically joined nucleotides that, as courts have recognized, constitute complex chemicals with uses and properties beyond those that occur naturally. Created DNA molecules constitute patentable subject matter because they are products of processes requiring substantial human intervention, which result in chemically and structurally altered substances with properties and uses that are vastly different from anything found in nature (C.A. App. A3708 at ¶ 29).

Moreover, created DNA molecules do not fit into any of the judicially-created exceptions against patenting laws of nature, physical phenomena, or abstract ideas since, unlike the areas those exceptions cover, isolated DNA molecules are substances created only as a result of human intervention and effort. Indeed, in order to create an isolated DNA molecule, a human must first use ingenuity to identify and define that molecule and then apply advanced technology to either chemically isolate that molecule from the host of surrounding genetic material in the body or synthesize that molecule (*see, e.g.*, C.A. App. A3708; A4320-22; A4770-72).

It is of no moment that created DNA molecules are themselves derived from other naturally occurring substances because they, like all chemical inventions, remain uniquely created substances that are the result of assembling materials found in nature. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012). Thus, patenting isolated DNA molecules does not run afoul of the purpose of these exceptions, which is to ensure that abstract concepts and qualities, rather than human engineered substances, remain free for all to use.

With regard to *Amici Curiae*, a broad ruling on the question before this Court may have sweeping ramifications with respect to the patentability of inventions derived from genetic materials of animals, plants, and viruses. For example, AHI's members, such as Merial, are focused on developing novel products for treating and preventing the diseases that affect the global animal population, which include products to protect the health of (i) production animals such as cows, poultry, swine, and sheep; (ii) pets such as dogs and cats; and (iii) wildlife. The work of AHI's members helps not only animals, but also serves to protect the health of the human population, sustain agriculture, and preserve the environment.

ARGUMENT

I. Public Policy Strongly Favors a Holding that Created DNA Molecules Constitute Patentable Subject Matter Under 35 U.S.C. § 101.

A. Ruling that created DNA molecules are not patentable would have a substantial adverse impact on innovation, including the investment-backed expectations of the animal health industry.

The United States patent system is founded on the principle that a limited right to exclude is the proper incentive and exchange for the publication of an invention. As succinctly put by Abraham Lincoln:

> Next came the patent laws. These began in England in 1624, and in this country with the adoption of our Constitution. Before then any

> man [might] instantly use what another man had invented, so that the inventor had no special advantage from his own invention. The patent system changed this, secured to the inventor for a limited time exclusive use of his inventions, and thereby added the fuel of interest to the fire of genius in the discovery and production of new and useful things.

Abraham Lincoln, Lecture 'Discoveries, Inventions and Improvements' (22 Feb 1860), in 5 Complete Works of Abraham Lincoln 113 (John George Nicolay and John Hay eds., 1894). Without this critical right to exclude, our 16th President recognized that innovators would be unable to protect their investment in inventions and thus would wither the progress of science and useful arts.

Merial and AHI's other members can afford to bring new animal health inventions to the public only if they can recoup the substantial upfront investments necessary to (i) discover, research, and develop inventions; (ii) conduct clinical trials and obtain regulatory approval for them; and (iii) market them to the public. Our patent system—as well as the systems in nearly every other developed nation—is designed to ensure that these substantial investments are recovered by granting patent protection for inventions to those that discover and develop new technologies for a limited period of time. Excluded from the marketplace are those who would reap the fruits of the research and development labor without having risked the initial investment.

It is important to consider that patents to created DNA molecules do not prevent humans from using their

genes in any of the ways that their genes have been used since the dawn of time. For example, the challenged patents do not rob humankind of a right or ability of which they were previously privy, such as transcribing DNA into mRNA within a human body.[4] To the contrary, patents to created DNA molecules merely protect uses of isolated DNA molecules, once removed from the natural environment, so that those isolated molecules can be put to useful purposes that did not previously exist.[5] The purpose of the patent system is to reward those inventions by providing innovators with a protective right to exclude.

This protection is the essence of patents. *See* U.S. Const. art. I, § 8, cl. 8; *see also Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1563 (Fed. Cir. 1995) ("Exclusivity in commercialization enables a patentee to recoup its investment in research, production, and marketing a new product."). This period of exclusivity is particularly important to the animal health industry because profit margins for most animal health products are relatively small, especially when compared to those in the human pharmaceutical industry. The ability of AHI member companies, such as Merial, to discover and obtain patent protection on created DNA molecules has been of enormous benefit to both animals and humans. The limited period of exclusivity afforded by patents on such molecules has permitted AHI's members to make the substantial

4. Although preemption was a concern in *Mayo*, that is not a concern here. The challenged patents concern specific isolated DNA molecules and do not preempt people from using human genes or the information contained in human genes.

5. To be patentable, isolated DNA molecules must also meet the utility requirement of § 101.

investments necessary to develop and bring to market a number of DNA-based products for the treatment and/or prevention of significant diseases affecting the global animal population.

For example, animal health products that have been developed, or are in the process of being developed, based on inventions involving created DNA molecules include a treatment for mammals who are suffering from acute or chronic renal failure and vaccines against numerous infectious animal diseases. Such DNA-based vaccines include those against West Nile virus, which infects birds, horses, dogs and cats, is widespread in Africa, and is known to infect and cause a seasonal epidemic in humans in North America; porcine reproductive and respiratory syndrome (PRRS) virus, which causes a disease in pigs that results in reproductive failure in pregnant sows and respiratory failure in neonatal pigs; infectious bursal disease virus, which causes a highly contagious disease of young chickens; equine herpesvirus, which can cause respiratory disease in horses; and feline caliciviruses, which is a principal source of upper respiratory tract conditions in cats. Created DNA molecules have significant utility; for instance they may function as probes and primers that allow scientists to determine the susceptibility of a subject to particular genetic disorders or, additionally, may serve as the fundamental building block in live vector vaccines (*see, e.g.,* C.A. App. A3813; A3840-41; A4322-23; A4728-29; A6771).

In addition to their own discoveries, AHI companies, including Merial, have entered into research collaborations with universities to discover and develop DNA-based inventions or have licensed from universities DNA-based

inventions that have already been discovered and patented by university scientists. Because universities may lack the resources necessary to bring products to market, they often license their discoveries to companies like Merial for development. These patent licensing arrangements provide the universities with much needed revenue streams while providing commercial entities with access to DNA-based inventions. These arrangements also benefit the public since they often result in the development of novel products for the treatment and prevention of serious diseases affecting the global animal population.

For example, Merial introduced the world's first vaccine aimed at preventing a devastating disease impacting the pork industry, Postweaning Multisystemic Wasting Syndrome ("PMWS"). Merial's vaccine was based on the pioneering work of scientists at Merial in collaboration with two universities, who were able to discover, isolate, and characterize DNA from a previously unknown type of virus that is responsible for PMWS. In developing such inventions, AHI member companies, including Merial, expect that they will receive a limited period of exclusivity flowing from the patents on their inventions. Without that expectation, AHI member companies could not justify the enormous upfront investments necessary to develop and commercialize these isolated DNA-based inventions. The AHI member companies' expectations of patent protection have been soundly justified by the practice of the PTO and the law of the Federal Circuit.

The PTO has granted patents directed to isolated DNA molecules for over 25 years (C.A. App. A3467 (n.11); A3710 at ¶ 35). The PTO's 2001 Utility Examination Guidelines themselves show that over the prior 10 years, the PTO

had issued at least 2,645 patents with claims to "isolated DNA" (C.A. App. A3467; A3710). Moreover, the Guidelines make clear that "[a] purified DNA *molecule* isolated from its natural environment . . . is a chemical compound and is patentable if all the statutory requirements are met." (C.A. App. A3973; *see also* A3971-72; 66 Fed. Reg. 1092, 1094 (Jan. 5, 2001) (emphasis in original)). In other words, the PTO has made clear its own policy of granting patent protection for inventions involving isolated DNA molecules. Moreover, when these patents have faced challenges, the Federal Circuit has upheld them. *See, e.g., In re Deuel*, 51 F.3d 1552, 1555, 1560 (Fed. Cir. 1995) (reversing rejection of claims directed to a "purified and isolated DNA sequence"); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) (affirming patentability of claims directed to, inter alia, a "purified and isolated DNA sequence"); *cf. In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009) (affirming obviousness determination of claim to DNA encoding a natural protein, without questioning that claim constituted patentable subject matter); *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993) (affirming award of priority of invention for a claim directed to a DNA molecule). AHI member companies have thus relied on the policies of the PTO and the holdings of the Federal Circuit to continue the research and development of, and to obtain patent protection on, the DNA-based inventions that benefit animals and humans worldwide.

Standing against this history of patent protection, the district court's ruling here threatens to disrupt severely the investment-backed expectations AHI members and other entities that rely on patent protection to justify the expense of developing DNA-based inventions. If that ruling were to stand, Merial and other AHI member

companies would be forced to consider the significant risk that, because DNA-based inventions would not be patentable, any meaningful investment in the development of those inventions might not be recoverable. In many instances, the district court's ruling would force AHI member companies to forgo any research into or the development of new DNA-based animal health products because the enormous upfront investment could not be justified.

B. Ruling that created DNA molecules are not patentable would create dissonance between the patent laws of the United States and those of the rest of the world.

Commentators and legislators alike have long recognized the benefits of global patent law harmonization. Over the past several decades, the United States has made several attempts to harmonize its patent law with global patent law, including the Paris Convention, the Patent Cooperation Treaty, and the Trade-Related Aspects of Intellectual Property Rights. Just two years ago, then Under Secretary of Commerce and Director of the PTO, David Kappos, made a call for this global harmonization: "I urge us all to begin the process of patent law harmonization anew, now. I urge us all to search for common ground. I urge us all to let best global policy and best practices be our guide." David Kappos, *A Global Call for Harmonization*, USPTO.GOV (April 5, 2011), *available at* http://www.uspto.gov/news/speeches/2011/kappos_london.jsp.

Less than six months later, Congress passed the Leahy-Smith America Invents Act ("AIA"), which

represents the latest, and the most significant, step toward global patent harmonization. The AIA implemented the recommendations of the National Academies of Science, which called for greater harmonization of domestic patent laws with those of other nations and implements several measures that bring United States' patent law closer to those of European and other nations. *See* S. Merrill, R. Levin & M. Myers, "A Patent System for the 21st Century" (2004).

Ruling against the patentability of created genetic molecules would set back the recent strides that have been made toward global patent harmonization, because many of the United States' largest trade partners allow for the patenting of created genetic molecules. For instance, in 1999, the European Patent Council incorporated provisions that allow for the patentability of biological material, such as DNA, if the material is isolated from its natural environment or produced by means of a technical process (*see* OFFICIAL JOURNAL OF THE EPO, Dec. of the Admin. Council of 16 June 1999 amending the Implementing Regulations to the European Patent Convention, *available at* http://archive.epo.org/epo/pubs/oj99/7_99/7_4379.pdf). Following the adoption of these provisions, the EPO, the administrative body that is responsible for granting European patents, has continued to issue patents on isolated genetic molecules, including those related to the patents before this Court (*see* European Patent Nos. 699,754; 705,903; 705,902; 785,216). Myriad was also granted related patents in Canada (*see* Canadian Patent Nos. 2,196,797; 2,196,790, and 2, 196,795), Australia (Australian Patent Nos. 686,004; 691,958), New Zealand (New Zealand Patent No. 326,525), and Japan.

Not only have international patent offices granted patents claiming isolated DNA molecules, the Federal Court of Australia recently upheld the patentability of Myriad's Australian patent which corresponds to the patent at issue before this Court *Cancer Voices Austl. v. Myriad Genetics Inc.*, FCA 65 (15 Feb. 2013), *available at* http://www.austlii.edu.au/au/cases/cth/FCA/2013/65.html. There, the Court found that isolated genetic material is patentable under Australian law. In so holding, the Australian Court remarked:

> It would lead to very odd results if a person whose skill and effort culminated in the isolation of a micro-organism (*a fortiori*, an isolated DNA sequence) could not be independently rewarded by the grant of a patent because the isolated micro-organism, no matter how practically useful or economically significant, was held to be inherently non-patentable.

Id. at ¶ 109.

Similarly, here, it would lead to "very odd results" if the United States' patent laws refuse to recognize the patentability of created genetic molecules, despite the consensus that has developed among some of the United States' largest trading partners that such created DNA molecules are patentable. For global innovators, such as Merial, with a number of closely related patents in numerous countries that are directed to particular inventions, it is critical for there to be uniformity between the United States' patent laws and those of other developed nations. Moreover, if the United States does not protect innovation in advanced technological fields such

as biochemistry, that technology will move overseas and this country will, as an inevitable result, suffer a global competitive disadvantage.

II. Created DNA Molecules Are Patentable Subject Matter under 35 U.S.C. § 101.

Above all, AHI's members justifiably rely on patent protection for isolated (*i.e.*, created) DNA-based inventions because it is correct as a matter of law. Section 101 provides: "[w]hoever 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[e] . . . ." 35 U.S.C. § 101. The Federal Circuit has characterized this Court's decisions as having "consistently construed § 101 broadly, explaining that '[i]n choosing such expansive terms . . . modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope.'" *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303 (Fed. Cir. 2013) (quoting *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010)). Applying this statutory framework, created nucleic acid molecules are patentable subject matter whether viewed as compositions of matter, manufactures, or any useful improvement thereof.

A. Created DNA molecules are compositions of matter or new and useful improvements thereof under § 101.

As the Federal Circuit correctly recognized, claims to created DNA molecules qualify as "compositions of matter" or "new and useful improvement[s] thereof" under § 101. *Ass'n for Molecular Pathology*, 689 F.3d at

1324-25. This Court has held that compositions of matter cover "all compositions of two or more substances and [includes] all composite articles, [including the] results of chemical union . . . ." *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

Isolated DNA molecules are a chain of organic compounds composed of nucleotides linked to a phosphate group (*see, e.g.,* C.A. App. A4290; A4313; A4317-19; A4322-25). These chemical entities therefore constitute compositions of matter under the *Chakrabarty* definition. Both the Federal Circuit and the PTO have correctly recognized that isolated DNA molecules are complex *chemicals*.[6] *See, e.g., Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d at 1206; *see also* PTO's 2001 Utility Examination Guidelines, 66 Fed. Reg. at 1093 (C.A. App. A3972) ("Like other chemical compounds, DNA molecules are eligible for patents when isolated from their natural state . . . ."). Thus, with respect to patent eligibility, created DNA molecules should be treated no differently than other human-made molecules that are derived from larger, naturally occurring, molecules.

Created DNA molecules are not identical to DNA as it exists in nature and thus, like other patent eligible human-made molecules, possess new forms, qualities, and properties that are not found in nature (C.A. App. A3707-08; A3709-10; A4322-24; A4412; A4413; A4414-15; A4418; A4424-25; 4728-29). *See also Ass'n for Molecular Pathology*, 689 F.3d at 1325 ("The isolated DNA molecules

6. At their most basic level, isolated DNA molecules are compositions of individual chemical elements, namely carbon, hydrogen, oxygen, nitrogen, and phosphorous (C.A. App. A4317).

before us are not found in nature."). Specifically, human DNA in its natural state is organized into chromosomes and comprises a long strand of millions of nucleotides (*see, e.g.,* C.A. App. A4320-22). This long strand forms a tightly coiled bundle with DNA binding proteins called histones. A particular DNA molecule within the chromosome is not identifiable or useful in its native form (*see* C.A. App. A3707-08; A4320-25). In contrast, the claimed nucleic acid molecules have a defined beginning and end, and exist independently of the DNA binding proteins and the additional millions of nucleotides of the chromosome (*see id.*). Further, in order to create an isolated DNA molecule, humans must first apply creativity to subjectively identify and define that molecule and then, using advanced technology, chemically excise that molecule from the surrounding genetic material (thus creating a new molecule that is not found in nature) (*see, e.g.,* C.A. App. A3708; A4320-22; A4770-72).

Thus, by the same reasoning advanced in *Chakrabarty*—that patentable subject matter had "markedly different characteristics from any [substance] found in nature," 447 U.S. at 310—the challenged claims[7] are patent eligible. In particular, as the Federal Circuit correctly recognized, "Although isolated DNA is removed from its native cellular and chromosomal environment, it has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body." *Ass'n for Molecular Pathology*, 689 F.3d at 1328. Accordingly, as complex chemicals composed of

7. The challenged claims include Claims 1, 2, and 5 of United States Patent No. 5,747,282 ("the '282 Patent"), in addition to the claims identified by Petitioners at Pet. App. 426-28a.

chemically joined nucleotides, created DNA molecules are patentable as new and useful compositions of matter, or at the very least as "new and useful improvements thereof," within the meaning of § 101.

B. Created DNA molecules are manufactures under § 101.

Even if created DNA molecules somehow did not fit within the definition of "compositions of matter" or "new and useful improvements thereof" (as they should), they qualify as "manufactures" under § 101. In particular, isolated DNA molecules are products of processes that result in chemically- and structurally-altered substances with vastly different properties and uses from the natural starting material. These are precisely the qualities of a "manufacture" as interpreted by the courts. *See Chakrabarty*, 447 U.S. at 308 (citing *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931)).

The claims are drawn to a particular chemical entity, not just to a DNA molecule. To find and create a particular isolated DNA molecule involves a significant degree of human manipulation and intervention because an inventor must, *inter alia*, (i) choose whether an isolated DNA molecule will be single or double stranded; (ii) define the length, complexity, and nucleotide composition of that molecule; and (iii) choose whether that molecule will be used as a primer (and thus will be designed to have a sequence that is the reverse complement of a region of target DNA and that has a particular melting temperature) (*see* C.A. App. A3707-08; A3878; A4324; A4341-4343). The resulting isolated DNA molecule is stripped of its chromosomal environment,

released of the strictures of the regulation of the cell, devoid of its native tertiary structure, and thus no longer serves the same function as it did in the human body. In short, the form and function of created DNA molecules is markedly different from DNA as it exists in the body.

Finding in § 101's language a clear indication that "Congress plainly contemplated that the patent laws would be given wide scope," this Court has adopted a "broad construction" of the term "manufacture." *Chakrabarty*, 447 U.S. at 308. Consistent with its dictionary definition, this Court has held that "manufacture" encompasses any "production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." *Id.* (citation and punctuation omitted).

Created DNA molecules are "manufacture[s]" under this definition since an "isolated DNA molecule" necessarily involves human intervention. The term "isolated" used in the context of a patent claim directed to an "isolated DNA molecule" ties the claimed invention to the production of a new and useful article, made through human intervention and innovation, that is different from anything found in nature (C.A. App. A4291; A4320-24; A4335; A4336-39). This is because created DNA molecules do not exist in nature, but rather are only created by human innovation in the laboratory (C.A. App. A4291; A4320-24; A4335; A4336; A4338-39).

The challenged patents teach that created DNA molecules must be either (i) chemically synthesized or (ii) chemically excised from the other sequences in the genome and from any proteins or other cellular

components, that naturally accompany the particular DNA sequence of interest (*see, e.g.*, '282 Patent, col. 19:8-18 (JA 859); *see also* C.A. App. A4291 ("[S]omeone of ordinary skill in the art would understand that 'isolated DNA' has been extracted from the cell and excised from the chromosome, or chemically synthesized.")). Accordingly, created DNA molecules are the product of human manufacturing.

Further, the manufacturing processes for creating isolated DNA molecules require substantial human involvement. Creating isolated DNA molecules, whether via chemical synthesis or excision, requires several involved and highly technical steps (*see, e.g.,* C.A. App. A3708; A4291; A4320-22; A4336; A4341-42; A4770-72). In fact, the creation of isolated DNA molecules relies on molecular-scale machinery such as restriction endonucleases, DNA polymerases, DNA ligase, reverse transcriptase, and other enzymes, that chemically alter DNA (*see, e.g.,* C.A. App. A132-33; A595-97; A612-14; A2469; A4336; A4341-42).

These laboratory techniques used to create isolated DNA molecules all result in chemical and structural changes to any starting material (C.A. App. A3707-08; A4322; A4324; A4336-37; A4412; A4424-25). For example, the common polymerase chain reaction ("PCR") process results in isolated DNA molecules that are chemically and structurally different from the individual nucleotide building blocks or from any naturally occurring gene (C.A. App. A3707-08; A3709; A4336; A4424-25). Likewise, the creation of isolated DNA molecules via chemical excision from a cellular environment results in a product that is structurally different from chromosomal DNA in its

natural environment (*see, e.g.*, C.A. App. A4321-22; A4324; A4338-39; A4424-25). Thus, the process of isolating DNA molecules gives "new forms" to the raw materials that existed at the start of the process. *Chakrabarty*, 447 U.S. at 308.

The resulting human-created DNA molecules also have new properties and uses that do not exist in nature (C.A. App. A4320-24, A4325, A4335- 39; A6769-71). For example, isolated DNA molecules can be cloned into expression vectors for purposes of creating vaccines against a particular disease (*see, e.g.,* U.S. Patent No. 6,368,601, col. 4:11-53). Isolated DNA molecules can also be used as probes in assays designed to diagnose a disease or as primers in PCR reactions (*see e.g., id.*, col. 5:14-23; C.A. App. A4322-23). Naturally-occurring genes simply cannot be used in these ways (C.A. App. A4323; A6769-71).

Any assertion that the creation of isolated DNA molecules is akin to mining a mineral in the earth or plucking a leaf from a tree is premised on misunderstandings of (i) the level of human intervention necessary to create isolated DNA molecules and (ii) the differences between isolated DNA molecules and anything found in nature. *See Intervet*, 617 F.3d at 1295 (Dyk, J., concurring in part and dissenting in part) ("It would be difficult to argue, for instance that one could patent the leaves of a plant merely because the leaves do not occur in nature in their isolated form."). Rather, because created DNA molecules only exist as a result of human intervention, and because their creation imparts new qualities, properties, and uses from any starting material found in nature, isolated DNA molecules are patentable as new manufactures under § 101.

III. Created DNA Molecules Are Not Excluded From Patent Protection Under Any of the Limited Judicially Created Exceptions.

Although § 101 is broad, *Amici Curiae* recognize that it is not unlimited. This Court has set forth only "three specific exceptions to § 101's broad patent-eligibility principles: 'laws of nature, physical phenomena, and abstract ideas.'" *Bilski*, 130 S. Ct. at 3225 (quoting *Chakrabarty*, 447 U.S. at 309). These specific exceptions were crafted to ensure that abstract "concepts" and qualities remain a "'part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.'" *Id.* (emphasis added) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U. S. 127, 130 (1948)). The Federal Circuit recognized these judicially created exceptions and correctly determined they were inapplicable to whether the challenged claims constituted patentable subject matter under § 101. *See Ass'n for Molecular Pathology*, 689 F.3d at 1234.

The Federal Circuit correctly held that isolated DNA molecules are not products of nature because, "[w]hile they are prepared from products of nature, so is every other composition of matter." *Ass'n for Molecular Pathology*, 689 F.3d at 1325. Neither this Court nor the Federal Circuit has held that "substances," such as isolated DNA molecules, should be excluded from the scope of § 101 simply because they are derived from "naturally occurring substances." These exceptions do not exclude from patent protection new and useful substances that are created only as a result of human intervention, even if those new and useful substances are derived from natural products. The *Funk Brothers* decision, for instance, does not prohibit

the patenting of compositions derived from naturally occurring substances, but merely expresses this Court's concern regarding the patenting of abstract concepts such as "laws of nature" or "phenomena of nature." *See Funk Bros.*, 333 U.S. at 130.

As Justice Frankfurter explained in his concurring opinion in *Funk Brothers*, the problem with the patent claims at issue there was that rather than claiming particular mixtures of compatible bacterial strains—which would have been patentable, even though those strains are found in nature—the patentee attempted to claim all combinations of strains having the abstract and natural phenomenon of non-inhibition. *See Funk Bros.*, 333 U.S. at 133 (Frankfurter, J., concurring). As Justice Frankfurter wrote, "[i]nsofar as the court below concluded that the packaging of a particular mixture of compatible strains is an invention and as such patentable, I agree . . . ." *Id.* Justice Frankfurter stated that the patentee's combination of strains did not satisfy this description. Rather, "[t]he strains by which [the patentee] secured compatibility are not identified and are identifiable only by their compatibility." *Id.*

Thus, the *Funk Brothers* Court's concern was not that the patentee's claims were directed at natural substances *per se*, but rather that the patentee was attempting to claim the abstract, concept or principle of inhibition, which the Court considered to be "part of the storehouse of knowledge of all men." *Id.* at 130; *see also id.* at 132 (holding "the discovery of the natural principle itself" is not invention). Gravity, for example, constitutes one of these abstract principles of nature that is part of the storehouse of knowledge. This Court suggested that

products derived from nature, as opposed to abstract principles, are patentable if as a result of the patentee's efforts they "acquire[] a different use" or an "enlargement of the range of their utility," or there is an "improve[ment] in any way [in] their natural functioning." *Id.* at 131.

This Court's subsequent decision in *Chakrabarty* confirmed that new compositions of matter may be patentable, even if they are derived from natural substances. Specifically, the *Chakrabarty* Court upheld the patentability of claims directed to a genetically engineered bacteria because the claims were not directed to a "natural phenomenon" but to "a product of human ingenuity having a distinctive name, character [and] use." *Chakrabarty*, 447 U.S. at 309-10 (citation and punctuation omitted). Claims to isolated DNA molecules do not give rise to the concerns that were at issue in *Funk Brothers*. Such claims are not claims to abstract "concepts," "principles," or "knowledge," but rather are directed to tangible chemicals, *i.e.* molecules, which as a result of human intervention have acquired different properties and uses from anything that exists in nature.

Moreover, the use of any information conveyed by the sequence of any isolated DNA molecules is not prohibited by virtue of any patent protection on the isolated DNA molecule itself. Scientists and others may use the sequence information conveyed by patented isolated DNA molecules in a variety of ways without infringing the patents, as is evidenced by the thousands of scientific papers published on the BRCA DNA sequences (*see, e.g.,* C.A. App. A3643-44; A5570-71). Because patents to isolated DNA molecules are not within any of the three specific exceptions to § 101's broad patent-eligibility principles and more generally

do not in any way restrict the "storehouse of knowledge available to all men," created DNA molecules constitute patentable subject matter under § 101.

IV. This Court Should Not Give Credence to Petitioners' Complaints About the Patent System.

In its opinion, the Federal Circuit correctly dismissed several of Petitioners' attempts to override logic with emotional pleas:

> [I]t is important to state what this appeal is not about. It is not about whether individuals suspected of having an increased risk of developing breast cancer are entitled to a second opinion. Nor is it about whether the University of Utah, the owner of the instant patents, or Myriad, the exclusive licensee, has acted improperly in its licensing or enforcement policies with respect to the patents. The question is also not whether i[t] i[s] desirable for one company to hold a patent or license covering a test that may save people's lives, or for other companies to be excluded from the market encompassed by such a patent—that is the basic right provided by a patent, *i.e.*, to exclude others from practicing the patented subject matter. . . . Those questions are not before us. It is solely whether the claims to isolated BRCA DNA . . . meet the threshold test for patent-eligible subject matter under 35 U.S.C. § 101 in light of various Supreme Court holdings, particularly including *Mayo*.

* * *

> We would further note, in the context of discussing what this case is not about, that patents on life-saving material and processes, involving large amounts of risky investment, would seem to be precisely the types of subject matter that should be subject to the incentives of exclusive rights. But disapproving of patents on medical methods and novel biological molecules are policy questions best left to Congress, and other general questions relating to patentability and use of patents are issues not before us.

Ass'n for Molecular Pathology, 689 F.3d at 1324-25.

Petitioners seek to reframe the issue before the Court to be whether human genes can be patentable. That is a red herring. The challenged patents do not attempt to patent human genes. As set forth above, this case concerns only whether an isolated molecule—which is not found in nature, which possesses characteristics markedly different from those found in nature, and which can be put to a new use that was not previously known—is eligible for patenting. As the Federal Circuit correctly held, that should, in fact, be the case.

CONCLUSION

For at least the foregoing reasons, this Court should affirm the decision of the Federal Circuit that reversed the district court's decision in this matter and confirm that claims to novel created DNA molecules can constitute patentable subject matter under § 101.

Respectfully submitted,

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