No. 12-398

IN THE
Supreme Court of the United States

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

v.

MYRIAD GENETICS, INC., *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR THE NANOBUSINESS COMMERCIALIZATION ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

The NanoBusiness Commercialization Association ("NanoBCA") submits this brief as amicus curiae in order to ensure that the United States continues to lead the world in the burgeoning field of nanotechnology—a leadership position achieved in large part due to the country's robust patent system that encourages private investment in high-risk, cutting-edge research and commercialization.[1]

About NanoBCA. NanoBCA is a 501(c)(6) trade organization dedicated to promoting the commercialization of nanotechnology and helping companies bring affordable, life-improving nanotech products to market. NanoBCA's vision is to ensure that the United States—its companies, universities and people—leads the world in the discovery and commercialization of nanotechnology, and that nanotechnology's benefits are delivered safely to all of society. Among its missions, NanoBCA advocates for continued U.S. investment in nanotechnology through the National Nanotechnology Initiative ("NNI")—the U.S. government's interagency

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[1] In accordance with Supreme Court Rule 37.6, amicus curiae states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the amicus curiae or its counsel. Petitioners have filed a letter of blanket consent to *amici* on January 2, 2013. Respondents granted consent to *amicus* on February 15, 2013, via electronic mail, a copy of which is being submitted herewith.

program launched in 2001 for coordinating research and development and enhancing collaboration in nanoscale science, engineering and technology. Congress codified and expanded the NNI by passing the 21st Century Nanotechnology Research and Development Act of 2003, Pub. L. No. 108-153, 117 Stat. 1923 (2003).

What is nanotechnology? "Nanotechnology is the understanding and control of matter at the nanoscale, at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications." NATIONAL SCIENCE & TECHNOLOGY COUNCIL, NATIONAL NANOTECHNOLOGY STRATEGIC PLAN 3 (2011). A nanometer is one-billionth of a meter. A human hair is approximately 80,000 to 100,000 nanometers wide. A DNA molecule is approximately 2.5 nanometers wide; its uncoiled length can range from several to millions of nanometers.

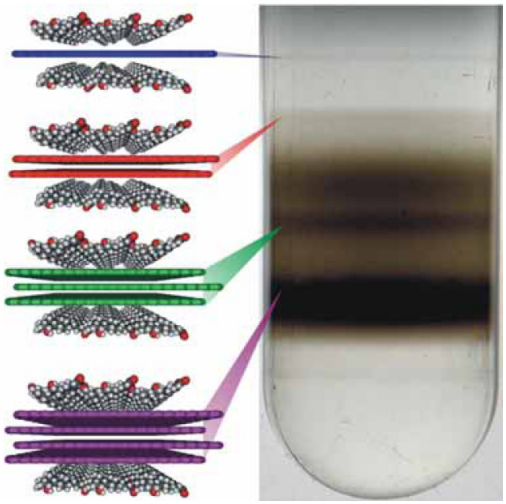
What is unique about nanomaterials that have been "isolated" from bulk materials? At the nanoscale, quantum physics begin to dominate the behavior and properties of materials. This quantum effect causes unusual physical, chemical, and biological properties to emerge when materials are reduced in size to the nanoscale. The properties of these man-made "nanomaterials" often differ in dramatic and unexpected ways from the properties of bulk materials found in nature, from which nanomaterials can be said to have been "isolated" (e.g., mechanically cleaved to remove surrounding bulk material, or synthesized to contain a tiny

fraction of the atoms or molecules found in bulk materials). There are numerous examples of man-made nanomaterials, "isolated," as it were, from their bulk constituents, which have enabled groundbreaking, real-world applications. Below are just a few examples.

- *Gold nanoparticles* can be thought of as "isolated" clusters of gold. At large scales, gold is shiny and yellow. But at the nanoscale, gold can vary in color from pink to red to purple depending on the size of the nanoparticles (seen below ranging from 5 to 100 nanometers in diameter). The unique properties of gold nanoparticles have enabled new diagnostic sensors and cancer therapies. For example, because gold nanoparticles selectively accumulate in tumors, they have enabled precise imaging and targeted laser destruction of tumors without harming surrounding healthy cells. *See* Nano.gov, What's So Special about the Nanoscale?, http://nano.gov/nanotech-101/special (last visited Mar. 4, 2013).

(Image of gold nanoparticles courtesy of nanoComposix)

- *Graphene* is, conceptually, an "isolated" form of graphite (graphite being a black, naturally-occurring form of carbon). Graphene consists of a single-atom-thick sheet of carbon that scientists have peeled from graphite's surface via mechanical cleaving or chemical exfoliation. Unlike large-scale graphite, however, nanoscale graphene is a near-perfect electrical conductor and, therefore, has attracted enormous attention for use in future-generation electronic devices. *See* Yanqing Wu *et al.*, *High-Frequency, Scaled Graphene Transistors on Diamond-like Carbon*, 472 NATURE 74 (2011). Scientists are now able to selectively isolate one-, two-, and three- atomic layers of graphene (seen below as blue, red, and green bands, respectively, in contrast to black graphite).



See Alexander A. Green & Mark C. Hersam, *Solution Phase Production of Graphene with*

Controlled Thickness via Density Differentiation, 9 NANO LETT. 4031 (2009).

SUMMARY OF ARGUMENT

The Court in this case should do two things. First, it should uphold the patent eligibility of Myriad's product claims under § 101. Second, and just as importantly, the Court should recognize patent law's longstanding "experimental use" exemption from infringement which allows the public to use a patented invention for the "purpose of philosophical [or 'scientific'] experiment, or to ascertain the verity and exactness of the [patent] specification," or for "ascertaining the sufficiency of the [invention] to produce its described effects," or "to experiment with and improve upon the patented subject matter." *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 527 (Fed. Cir. 2012); *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391) (Story, J.); *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) (Story, J.).

In so holding, the Court would strike the right balance between encouraging investment in early stage technology and ensuring that patents do not block follow-on research aimed at studying, improving upon, or designing around the patented inventions. NanoBCA submits that it is better to allow broad patent eligibility and to simultaneously clarify the scope of the experimental use doctrine, as opposed to denying patent eligibility outright, which could chill investment in early stage technology, including nanotechnology.

ARGUMENT

I. COMPOUNDS ISOLATED BY MAN, WHICH DO NOT EXIST IN NATURE IN ISOLATED FORM, YIELDING NEW COMMERCIAL USES, ARE PATENT ELIGIBLE UNDER § 101

When Congress enacted 35 U.S.C. § 101 as part of the Patent Act of 1952, Congress explained that patentable subject matter in that section "include[s] anything under the sun that is *made by man*." S. REP. NO. 82-1979, at 5 (1952) (emphasis added); H.R. REP. NO. 82-1923 (1952) (emphasis added). A product of nature is clearly not patent eligible under § 101 because it is not "made by man" but is made by Nature itself.

Following Congress' directive, this Court has reiterated that the dividing line between an unpatentable "product of nature" and a patent eligible "invention" under § 101 is *human ingenuity*:

> As this Court held in *Chakrabarty*, "the relevant distinction" for purposes of § 101 is not "between living and inanimate things, but between products of nature, whether living or not, and *human-made inventions*."

J.E.M. Ag Supply v. Pioneer Hi-Bred Int'l, 534 U.S. 124, 134 (2001) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980) (emphasis added).

This Court's clear distinction between patent-eligible "products of human invention" and patent-

ineligible "products of nature," *J.E.M.*, 534 U.S. at 134, rests on a well-established framework that has long encouraged chemists, biologists, and materials scientists to isolate and purify active natural ingredients, which do not exist naturally in isolated and purified form, and when so modified, unlock new commercial uses unavailable in nature.

A. "Isolated" and "Purified" Forms of Natural Products Have Long Been Patent Eligible

In 1877, Louis Pasteur was issued U.S. Patent No. 141,072, titled "Improvement in the Manufacture of Beer and Yeast." The patent specification explains that Pasteur discovered that "pernicious germs," naturally present in brewer's yeast, was what caused beer and other products made from yeast to spoil or "vary in condition." U.S. Pat. No. 141,072, p. 1 (issued Jul. 22, 1873). By eliminating these germs, "beer may be produced which shall not vary in condition at any temperature." *Id.* at 1. The specification stressed that "[t]he employment of *pure yeast . . . is of prime necessity*—that is to say, yeast deprived of the germs by which the beer is liable to be affected." *Id.* p. 2 (emphasis added). Thus, in addition to claiming the method he used to obtain pure yeast, Pasteur's patent also claimed: "*Yeast, free from organic germs of disease, as an article of manufacture*." *Id.* p. 3, cl.2 (emphasis added).

In 1892, the Second Circuit in *Blumenthal v. Burrell* upheld the validity of a patent on a purified form of chymosin, an enzyme found in the stomach of

pigs and used to curdle milk in the manufacture of cheese. 53 F. 105 (2d Cir. 1892). In nature, chymosin is always present with another enzyme, pepsin. The patent-in-suit claimed "chymosin separated from pepsin, and uncombined with foreign substances." *Id.* at 107. When "separated" as claimed, these enzymes "are perfectly soluble in water, and form tasteless and odorless and clear or limpid solutions that do not readily decompose." *Id.* at 106. Thus, despite the fact that chymosin "had long been used to curdle milk in the manufacture of cheese," the Second Circuit upheld the claim for purified chymosin, which the court held "was not merely an improved, but an absolutely new, article, having its own distinctive nature." *Id.* at 107.

In 1910, the Second Circuit in *Union Carbide Co. v. American Carbide Co*. upheld a claim to calcium carbide in crystalline form, which had existed previously only in amorphous (noncrystalline) form. 181 F. 104 (2d Cir. 1910). In both forms, however, calcium carbide has the identical chemical formula: CaC_2. *Id.* at 105. And in both forms, calcium carbide is useful in the production of acetylene gas. *Id.* But, unlike in amorphous form, crystalline calcium carbide "is more durable . . . hard, compact, and so unlike the [amorphous] powdery mass as almost to amount to a new body." *Id.* at 107. The court reasoned, "To hold an important discovery which has given to the world a commercially new product—a product the high utility of which must be conceded—not entitled to protection for want of novelty, would, as it seems to us, be applying the patent statute to defeat its fundamental purposes." *Id.* at 108.

That same year in *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, the Seventh Circuit sustained a patent directed to "Aspirin"—acetylsalicylic acid in "substantially pure" form. 179 F. 701, 704 (7th Cir. 1910). The court accepted the defendant's assertion that acetylsalicylic acid, having "the same chemical formula" as the claimed compound, had previously been produced in impure form. *Id.* Those impurities, however, render the acid "undesirable or unsafe, if effective at all, in therapeutics." *Id.* In upholding the claim to the purified version, the court stated, "*it makes no difference, so far as patentability is concerned, that the medicine thus produced is lifted out of a mass that contained, chemically, the compound*; for, though the difference between [the patent] and [the prior art] be one of purification only—strictly marking the line, however, where the one is therapeutically available and the others were therapeutically unavailable—patentability would follow." *Id.* at 105 (emphasis added).

In 1911, Judge Billings Learned Hand, then a trial judge, authored *Parke-Davis & Co. v. H. K. Mulford Co.*, upholding a patent to a purified extract of animal adrenal glands "practically free from inert and associated gland-tissue." 189 F. 95, 98 (S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912). Before the Patent Office, counsel for applicant persuaded the examiner that "the substance as claimed is distinguished from the glands by the [claim] language that it is in stable and concentrated form and free from inert constituents." *Park-Davis*, 196 F. 496 (Transcript of

Record, No. 4363, Box 1684, at 851-853). At trial, defendants sought to invalidate the patent on the ground that "the patent [was] only for a degree of purity, and therefore not for a new 'composition of matter.'" *Parke-Davis*, 189 F. at 103. Judge Hand responded that "no one had ever isolated a substance which was not in salt form, and which was anything like" the patented product. *Id.* Judge Hand went on to famously say:

> But, *even if it were merely an extracted product without change, there is no rule that such products are not patentable*. Takamine was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while *it is of course possible logically to call this a purification of the principle*, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent.

Id. (emphases added).

In 1958, the Fourth Circuit in *Merck & Co. v. Olin Mathieson Chemical Corp.* reversed a district court's invalidation of several product claims on "product of nature" grounds. 253 F.2d 157 (4th Cir. 1958). The claims covered a purified form of vitamin B-12 obtained from fungi fermentation. Vitamin B-12 is produced naturally in minute quantities in the liver of cattle and in certain microorganisms. *Id.* at 161. These natural forms of vitamin B-12, the court

found, have "no utility, therapeutically or commercially, until converted into compositions comparable to the patented products." *Id.* Moreover, "[vitamin B-12] did not exist in nature in the form in which the patentees produced it." *Id.* at 164. Citing *Union Carbide*, *Kuehmsted*, and *Parke-Davis*, the Fourth Circuit held:

> The compositions of the patent here have all of the novelty and utility required by the [Patent] Act [of 1952] for patentability. They never existed before; there was nothing comparable to them. *If we regard them as a purification of the active principle in natural fermentates, the natural fermentates are quite useless*, while the patented compositions are of great medicinal and commercial value. The step from complete uselessness to great and perfected utility is a long one.

Id. (emphasis added).

These cases established the well-settled rule that natural compounds, isolated and purified by man, which do "not exist in nature in the form" claimed (*Merck*)—and despite having "the same chemical formula" (*Kuehmsted*) or having been "extracted . . . without change" (*Parke-Davis*)—are patent-eligible human-made inventions, so long as they yield a new and improved utility over Nature. As such, the isolated/purified compounds are deemed "a commercially new product" (*Union Carbide*) "a new

thing commercially and therapeutically" (*Parke-Davis*).[2]

B. The Word "New" in § 101 is Defined in § 102 and Nowhere Else

Section 101 requires patentable inventions to be "new and useful." But the word "new" in § 101 does not allow courts to expand its meaning beyond the novelty requirement of § 102. As Congress explained when it enacted both of these sections, "Section 102 . . . includes, in effect, an amplification and *definition of 'new' in section 101*." S. REP. NO. 82-1979, at 6 (emphasis added); H.R. REP. NO. 82-1923, at 7 (emphasis added).

Prior to 1952, a single statutory provision governed both patent eligibility and patentability (R.S. § 4886, codified at 35 U.S.C. § 31). In the Patent Act of 1952, this old provision was "split into two sections, section 101 relating to the subject matter for which patents may be obtained, and section 102 defining statutory novelty and stating other conditions for patentability." S. REP. NO. 82-1979, at 17; H.R. REP. NO. 82-1923, at 17.

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[2] *See* EDWARD THOMAS, CHEMICAL PATENTS AND ALLIED PATENT PROBLEMS, 32 (John Byrne & Co. 1917) ("A product may be patentable because of its utility even if merely purer or in more useful form than the prior art shows."); *id.* at 33 ("A product may be patentable because it has hitherto been unattainable . . . ."); *id.* at 34 ("It is the utility which is controlling, and a composition having new utility, not previously obtainable by those skilled in the art is patentable even though it differs from another only in degree.").

The fact that, prior to 1952, patent eligibility and novelty resided in the same statutory section explains some of today's confusion, seen in various briefs submitted to this Court, which tend to conflate these two distinct requirements when relying on earlier cases, but which cases were clearly decided on lack of novelty grounds, not on patent-eligibility grounds. *See, e.g.*, *Am. Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. 566, 596 (1874) (holding that patent on cellulose derived from wood was "void for want of novelty"; "no substantial difference is discoverable"; "the product was in no sense new"); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 308, 311 (1884) (citing *American Wood-Paper* to hold that artificial alizarine—claimed "not as a new substance prepared for the first time, but as the substance already known as alizarine"—was an "old article," indeed a "well known substance").

C. Sufficiency of "Differences" Between a Man-Made Compound and Its Natural Precursor is Measured under § 103

Chakrabarty stated that the man-made bacteria at issue in that case exhibited "*markedly different* characteristics from any found in nature." 447 U.S. at 310 (emphasis added). But *Chakrabarty* did not hold that the existence of "markedly different characteristics" is always a necessary condition under § 101. Nor did the Court attempt to lay out any fact-intensive framework for deciding in future case whether differences between a claimed and natural product are sufficiently different to be regarded as "markedly" different. Indeed, technical

fact-finding of this sort is not suitable to § 101, which has always been a pure question of law.

Fortunately, Congress has provided an exact (and only) standard for weighing any "differences" that may exist between what a patent claims to be new and what the world knows to be old. Section 103 asks "if the *differences* between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a) (emphasis added). Section 103 involves "several basic factual inquiries," treated as questions of fact, that underlie the ultimate legal question of obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) (identifying such factors as "[1] the scope and content of the prior art . . . [2] differences between the prior art and the claims at issue . . . [3] the level of ordinary skill in the pertinent art . . . . [4] secondary considerations").

Section 103 is, therefore, the only appropriate test for weighing the sufficiency of any "differences" between a man-made product and the natural building blocks from which the product is derived. Since all patents must pass through § 103, it applies with equal force to claims on isolated DNA. *See In re Kubin*, 561 F.3d 1351, 1354 (Fed. Cir. 2009) (affirming as obvious a claim to an isolated DNA sequence, even where the exact sequence could not have been predicted, since the claimed sequence could readily have been obtained using convention

techniques, with knowledge of mouse versions of human receptor proteins).

D. *Funk Brothers* Dealt with Pre-1952 Act "Invention" (Today's § 103 Obviousness), Not § 101 Patent Eligibility

Petitioners and the United States are wrong to characterize *Funk Brothers* as a "Section 101" case. Pet. Br. 28; U.S. Br. 14-15.

Section 101 did not exist in 1948 when *Funk Brothers* was decided. More importantly, *Funk Brothers* did not deal whatsoever with patent eligibility but instead addressed the requirement of "invention" or "discovery"—today's nonobviousness requirement. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948) (holding that "the product claims do not disclose an *invention or discovery* within the meaning of the patent statutes" (emphasis added)). In setting forth the rule that a patentable product must "satisfy the requirement of invention or discovery," *id.* at 131, *Funk Brothers* cites *Cuno Engineering*, a case involving mechanical cigar lighters—not anything resembling a product of nature. *Cuno Eng'g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 85-86 (1941) (the "claims in question are for improvements in lighters, commonly found in automobiles, for cigars, cigarettes and pipes"). And *Cuno Engineering* in turn traces the origin of the "invention" requirement to *Hotchkiss*: "Since *Hotchkiss v. Greenwood*, [52 U.S. 248] 11 How. 248, 267, decided in 1851, it has been recognized that if an improvement is to obtain the

privileged position of a patent more ingenuity must be involved than the work of a mechanic skilled in the art." *Cuno Eng'g*, 314 U.S. at 90.

In 1952, Congress for the first time codified the common-law "invention" requirement as the new statutory nonobviousness requirement of § 103. The Committee Reports state that one of the "major changes" in the 1952 Patent Act was "incorporating a *requirement for invention* in § 103." S. REP. NO. 82-1979, at 4 (emphasis added); H.R. REP. NO. 82-1923, at 5 (emphasis added). This Court has explained that in enacting § 103, "Congress has emphasized 'nonobviousness' as the operative test of the section, rather than the less definite 'invention' language of *Hotchkiss* [*v. Greenwood*, 52 U.S. 248 (1851)] that Congress thought had led to 'a large variety' of expressions in decisions and writings." *Graham*, 383 U.S. at 14 (quoting S. REP. NO. 82-1979, at 6; H.R. REP. NO. 82-1923, at 7).

Properly viewed in this light, *Funk Brothers* is a classic case of a non-inventive, or § 103 obvious, combination of individually known elements (six known bacteria cultures), combined using conventional techniques (mixing and packaging), with no change in each element's respective function (each culture inoculating the same crop it inoculates separately). It is a textbook example of pre-1952 "lack of invention," or post-1952 obviousness. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) ("The combination of familiar elements according to known methods is likely to be obvious

when it does no more than yield predictable results.").

E. *American Fruit Growers* Interpreted "Manufacture," and Not "Composition of Matter"

The sole question in *American Fruit Growers, Inc. v. Brogdex Co.* was:

> Is an orange, the rind of which has become impregnated with borax, through immersion in a solution, and thereby rendered resistant to blue mold decay, a *"manufacture," or manufactured article*, within the meaning of § 31, Title 35, U.S. Code?

283 U.S. 1, 11 (1931) (emphasis added). The Court answered in the negative, relying on the dictionary definition of "manufacture," defined as "'the 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.* (quoting CENTURY DICTIONARY). Because the addition of borax to the rind did not change "the name, appearance, or general character of the fruit," and remained "fit only for the same beneficial uses as theretofore," it did not qualify as a "manufacture." *Id.* at 11-12.

By contrast, *Chakrabarty* squarely addressed the "composition of matter" category of § 101. The Court observed that "'composition of matter' has been construed consistent with its common usage to

include 'all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.'" *Chakrabarty*, 447 U.S. at 308 (quoting *Shell Development Co. v. Watson*, 149 F.Supp. 279, 280 (D.C. Cir. 1957) (citing 1 A. DELLER, WALKER ON PATENTS § 14, p. 55 (1st ed. 1937))). In holding that "respondent's micro-organism plainly qualifies as patentable subject matter," and not an unpatentable product of nature, the Court explained that the "claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'" *Id.* at 309-310 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

F. Myriad's Isolated DNA Claims Do Not Cover "Products of Nature"

Isolated DNA is not a "product of nature" since it is made "isolated" only through human ingenuity and manipulation. No natural thing can possibly infringe a patent on isolated DNA since no natural thing possesses DNA in isolated form. Also, isolated DNA is commercially useful in a way that native DNA is not: it allows individuals to be tested for diseases outside the human body. This utility is possible only when DNA is isolated; otherwise, DNA is entirely useless for such purpose in its native state, as Petitioners concede. Pet. Br. 9 ("It is not currently possible to use genes, including looking at

or sequencing them, without removing or 'isolating' them from the body.").

Congress recently took up the issue of "gene patents" in the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 27(a), 125 Stat. 338 (2011). Rather than categorically excluding them from patent protection (as it did with patents encompassing a "human organism"[3] or a method of "reducing, avoiding, or deferring tax liability"[4]), Congress instead directed the U.S. Patent and Trademark Office to "conduct a study on effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist." *Id.* at § 27(a). Thus, Congress expressly recognized that "gene patents . . . exist," and instead of banning them like it did with other technologies, decided that more study was needed. Informed by this study (or not), Congress is free to amend § 101 so as to exclude from patent protection isolated DNA. *Cf. Chakrabarty*, 447 U.S. at 318 ("Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering."). "But, until Congress takes such action, this Court must construe the language of § 101 as it is." *Id.*

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[3] *Id.* at § 32(a) ("[N]o patent may issue on a claim directed to or encompassing a human organism.").

[4] *Id.* § 14(a) ("[A]ny strategy for reducing, avoiding, or deferring tax liability, whether known or unknown at the time of the invention or application for patent, shall be deemed insufficient to differentiate a claimed invention from the prior art.").

Whether ultimately Myriad's claims are *patentable*, however, is a different question entirely. NanoBCA takes no position on whether the claims satisfy the requirements of novelty (§ 102), nonobviousness (§ 103), written description and enablement (§ 112 (a)), definiteness (§ 112 (b)), or any of the other "conditions or requirements of this title" which may preclude patentability. 35 U.S.C. § 101.

II. PATENTS DO NOT PREEMPT OTHERS FROM EXPERIMENTING ON, IMPROVING UPON, OR DESIGNING AROUND A PATENTED INVENTION

Petitioners assert that Respondents' patents "preempt" others from studying BRCA genes, using them to develop better tests or treatments, or discovering new uses for them in the detection of other cancers. Pet. Br. 2-3, 25, 40-48. This Court should dismiss these arguments and expressly recognize patent law's longstanding infringement defense based on "experimental use," first articulated by Justice Joseph Story in 1813, and followed by various lower courts. *See Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

This common law exception shields follow-on researchers from infringement liability in much the same way that a second, common law "experimental use" exception shields patentees from invalidity. The latter exception is likewise traced to Justice Story and is firmly established in this Court's

precedents. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998) ("[A]n inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention—even if such testing occurs in the public eye.").

A. This Court Recognizes an "Experimental Use" Exception for Patentees

In 1825, Justice Story, sitting as circuit justice in *Mellus v. Silsbee*, wrote that an inventor's patent should not be found invalid for lack of novelty if the inventor had licensed "a few persons" to use his invention in order to "ascertain its utility" prior to applying for the patent. 16 F. Cas. 1332, 1334 (C.C.D. Mass. 1825) (No. 9404). Justice Story revisited this theme twice more as circuit justice, explaining again that an inventor's own experiments, though conducted in public view, "would not take away his right to a patent" for lack of novelty, so long as the use of the invention was "merely experimental, to ascertain the value or utility, or success of the invention, by putting it in practice." *Wyeth v. Stone*, 30 F. Cas. 723, 726 (C.C.D. Mass. 1840) (No. 18,107); *Ryan v. Goodwin*, 21 F. Cas. 110, 111 (C.C.D. Mass. 1839) (No. 12,186).

This Court adopted the above view in *Elizabeth v. Pavement Co.*, holding that an inventor's public experimentation on an invention (in that case, an improved street pavement tested in plain sight) was not an invalidating "public use" within the meaning of the statute, "so long as the inventor is engaged, in good faith, in testing its operation." 97 U.S. 126, 135

(1878). "He may see cause to alter it and improve it, or not. His experiments will reveal the fact whether any and what alterations may be necessary." *Id.* "[A] bona fide effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended," is not an invalidating public use. *Id.* at 137. But "[a]ny attempt to use [the invention] for a profit, and not by way of experiment, . . . would deprive the inventor of his right to a patent." *Id.*

As recently as 1998, this Court in *Pfaff* stated, "The law has long recognized the distinction between inventions put to experimental use and products sold commercially." 525 U.S. at 64 (citing *Elizabeth*, 97 U.S. at 137). Looking back at the doctrine over nearly two centuries, the Court commented favorably that "[t]he experimental use doctrine, for example, has not generated concerns about indefiniteness." *Id.* at 67.

B. Since 1813, Lower Courts Have Recognized an "Experimental Use" Exception for Follow-On Researchers

Justice Story is also widely credited [5] with establishing an experimental use defense to patent infringement. Exactly two centuries ago, Justice Story sat as circuit justice in *Whittemore v. Cutter*, a case in which a patentee appealed a jury instruction that would have limited infringement to situations where an infringer had constructed an accused

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[5] *See, e.g.*, Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1023 (1989).

device that was "fit for use, and with a design to use it for profit." 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600). While acknowledging that this instruction was "certainly favorable to the defendant," Justice Story sustained this portion of the instruction on the basis that

> it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for *philosophical experiments*, or for the purpose of *ascertaining the sufficiency of the machine to produce its described effects*.

Id. (emphases added). Notably, the word "philosophical" in Justice Story's day meant "scientific."[6]

That same year, in *Sawin v. Guild*, Justice Story, sitting again as circuit justice, revisited the experimental use defense and set forth the rule that infringement requires

> the making [of the invention] with an intent to use [it] for profit, and not for the mere purpose of *philosophical experiment,*

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[6] *See* Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917, 929 (2004) ("Multiple authorities confirm that in Story's day philosophical meant scientific. At that time the noun philosophy referred to natural philosophy, which in turn meant science generally.").

> *or to ascertain the verity and exactness of the [patent] specification*.

21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391) (emphasis added).

In 1818, this Court in *Evans v. Eaton*, a patent case, appended to its decision a comprehensive summary of the state of patent law, which included Justice Story's language (who was a member of the Court at the time) that "the making of a patented machine *fit for use, and with a design to use it for profit*, in violation of the patent right, is, of itself, a breach of this section, for which an action lies." 16 U.S. 454, app. 26 (1818) (citing *Whittemore*, 29 F. Cas. at 1121) (emphasis added).

In subsequent years, Justice Story's experimental use defense to patent infringement gained general acceptance in case law and treatises.[7] Defendants have successfully raised it to escape infringement in a number of cases over the years.[8] The Federal Circuit, in two cases where the defense

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[7] *See, e.g.*, *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279) (calling the doctrine "well-settled"); 3 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898, at 55-57 (Boston, Little, Brown & Co. 1890) (restating the doctrine).

[8] *See, e.g.*, *Chesterfield v. United States*, 141 Ct. Cl. 838, 845-46 (1958); *Ordnance Engineering Corp. v. United States*, 84 Ct. Cl. 1, 4 (1936); *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 703 (D. Colo. 1935), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936); *Beidler v. Photostat Corp.*, 10 F. Supp. 628, 630 (W.D.N.Y. 1935); *Poppenhusen v. N.Y. Gutta Percha Comb Co.*, 19 F. Cas. 1059, 1063 (C.C.S.D.N.Y. 1858) (No. 11,283).

was raised, found it not to apply to the particular facts in those cases.[9] Scholars nevertheless agree that these two holdings by the Federal Circuit are correct, even if dicta in those cases suggests a narrower defense than originally contemplated by Justice Story, given that in both cases the defendants used the patented inventions—not to study, or improve upon, or design around the patented inventions, as Justice Story would have permitted—but as a thing the defendants knew to be fit for its intended purpose, and used as such.[10]

Last year, the Federal Circuit in *In re Rosuvastatin Calcium Patent Litigation*, returned to Justice Story's original, broad exception laid out in *Whittemore* (quoting in full his experimental use language) to reaffirm the broad view that "patenting does not deprive the public of the right to *experiment with and improve upon* the patented subject matter." *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 527 (Fed. Cir. 2012 (emphasis added).[11]

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[9] *Madey v. Duke University*, 307 F.3d 1351, 1362-63 (Fed. Cir. 2002); *Roche Products, Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984).

[10] *See* Harold C. Wegner, *Post*-Merck *Experimental Use and the "Safe Harbor,"* 15 FED. CIR. B.J. 1, 13, 15 (2005); Mueller, 56 BAYLOR L. REV. at 933-34, 940-41.

[11] *See also Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1375 (Fed. Cir. 2012) (Rader, C.J., dissenting) (explaining that "patents properly remain a *tool for research and experimentation* because the system encourages publication and sharing of research results") (emphasis added).

C. This Court Should Likewise Recognize that Patents Do Not Preempt Follow-On Research

Just as a *patentee* may "conduct extensive testing without losing his right to obtain a patent for his invention," *Pfaff*, 525 U.S. at 64, so too may the *public* use a patented invention

- for the "purpose of philosophical [or 'scientific'] experiment,"
- "to ascertain the verity and exactness of the [patent] specification,"
- to "ascertain[] the sufficiency of the [invention] to produce its described effects," or
- "to experiment with and improve upon the patented subject matter."

Rosuvastatin, 703 F.3d at 527; *Sawin*, 21 F. Cas. at 555; *Whittemore*, 29 F. Cas. at 1121.

These two doctrines operate in parallel to negate or exclude "experimental use" from the word "use" in § 102(b) (novelty) and the word "uses" in § 271(a) (infringement), which have appeared together in essentially the same form since the nation's first patent act. *See* Patent Act of 1790, ch. 7, §§ 1, 4, 1 Stat. 109, 110, 111 (1970) (novelty: "not before known or *used*" (emphasis added); infringement: "[i]f any person or persons shall devise, make, construct, *use*, employ, or vend" (emphasis added)).

Besides sharing historical origins in Justice Story, the two experimental use doctrines promote similar policy goals: facilitating scientific research

for the purpose of ensuring that patented inventions are properly understood, perfected, and improved upon—whether by the patentee or by the public. *See Elizabeth*, 97 U.S. at 135 (stating that a patentee may "test the [invention], and ascertain whether it will answer the purpose intended, and make such alterations and improvements as experience demonstrates to be necessary"); *Rosuvastatin*, 703 F.3d at 527 (stating that the "public [has] the right to experiment with and improve upon the patented subject matter").

Given that the patentee's exception "has not generated concerns about indefiniteness," *Pfaff*, 525 U.S. at 64, there is no reason why an infringer's experimental use defense, as envisioned by Justice Story, would not be as definite and workable as the patentee's exception. For example, the Federal Circuit has identified thirteen objective factors for determining if a patentee's public use is experimental, *see Electromotive Div. of Gen. Motors Corp. v. Transp. Sys. Div. of Gen. Elec. Co.*, 417 F.3d 1203, 1213 (Fed. Cir. 2005), and many of those same factors are equally relevant to an infringer's experimental use defense. *See* Andrew S. Baluch, Note, *Relating The Two Experimental Uses In Patent Law: Inventor's Negation And Infringer's Defense*, 87 B.U. L. REV. 213, 248 (2007) (identifying common factors). In both cases, experimental use is limited in scope to activities that are "primarily experimental and not commercial," and ends when the researcher knows that the invention, or improvement thereon, "will work for its intended purpose." *Id.* at 250-52 (citing cases). The follow-on

researcher is then entitled to obtain a patent on the improvement, at which point the original patentee must cross-license with the latter to market the improved technology, and vice versa.[12]

In the context of "research tools" (including "DNA sequences" used as diagnostic tools), the National Institutes of Health ("NIH") have determined that applying the common law experimental use defense to such tools would be relatively straightforward. REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS (1998). In particular, the NIH found there to be a "sensible distinction" between

> experimenting *on* a patented invention—i.e. using a patented invention to study the underlying technology or perhaps to invent around the patent, which is what the exemption covers—and experimenting *with* a patented invention to study something else, which the exemption does not cover.

Id. at app. D.

On a comparative note, the United Kingdom, Germany, Japan, China, Korea, Hong Kong, Canada,

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[12] *See, e.g.*, Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 860-62 (1990) (explaining the concept of "blocking patents" where "one patentee has a broad patent on an invention and another has a narrower patent on some improved feature of that invention").

and many other countries have recognized an experimental use defense to patent infringement. *See* NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES OF SCIENCES (NAS), A PATENT SYSTEM FOR THE 21ST CENTURY 111-12 (Stephen A. Merrill, Richard C. Levin, and Mark B. Myers, eds., 2004). That this Court has not yet had an opportunity to consider and endorse Justice Story's defense has, some believe, provided "incentives for certain industries—specifically, those conducting commercial research on patented technologies hoping to obtain patentable improvements—to locate their research operations outside of the United States." John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685, 719 (2002).

Thus, any pronouncement by this Court that patents "preempt" research aimed at studying or improving upon patented subject matter would mark a significant expansion of the traditional notion of infringement (and a significant narrowing of the traditional research exemption). Such a pronouncement, moreover, would disrupt settled expectations among university researchers who have long assumed that their basic research activities are shielded from infringement liability. *See* NATIONAL RESEARCH COUNCIL, at 109 (finding that a "research exception" had been "widely assumed, especially by academic investigators and research administrators, to shield scientific investigation at universities from lawsuits").

CONCLUSION

For the foregoing reasons, NanoBCA urges the Court to affirm the judgment of the court of appeals.

Respectfully Submitted,

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