No. 12-398

In The
Supreme Court of the United States

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 OF FIFTEEN LAW PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

JOSHUA D. SARNOFF
Counsel of Record for Amici Curiae
DEPAUL UNIVERSITY
COLLEGE OF LAW
25 E. Jackson
Chicago, IL 60604
(312) 362-6326
jsarnoff@depaul.edu

January 31, 2013

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INTERESTS OF *AMICI CURIAE*

This brief is filed on behalf of the undersigned Law Professors identified in the Appendix.[1]

Law Professors teach and write about patents, intellectual property, and constitutional law. Law Professors are concerned that the Court should clearly state the requirements for an eligible invention modifying or applying a natural discovery. These are that: (1) the claim must be for a *creative* "inventive concept" that is *not analogous* to (is *markedly different* from) the natural discovery's structure and functions; and (2) the ineligible discovery must be treated *as if it were prior art* when evaluating whether such an inventive concept exists. Given this standard, Law Professors are concerned that thousands of claimed DNA molecules based on discovered gene sequences – including those at issue – have never been patent eligible inventions but have been issued as patents that have chilled scientific and medical innovation. This Court should clarify the standard for eligibility to avoid needless and costly litigation and foregone innovation.

[1] The Petitioners' letter of consent for amicus briefs is on file with the Court; the Respondents' emailed consent accompanies this brief. This brief was not authored in whole or in part by counsel for any party. No one other than *Amici* and their counsel made a monetary contribution to preparing or submitting this brief.

SUMMARY OF THE ARGUMENT

In *Mayo Collaborative Services v. Prometheus Laboratories*, this Court reiterated that to be a patent eligible invention under Section 101 of the Patent Act, a claimed application of a natural discovery must reflect an "'inventive concept.'" In the 1952 Act, Congress restored for process claims this Court's "non-analogous" structure and function standard from *Ansonia Brass & Copper Co. v. Electric Supply Co*. When doing so, Congress also codified the corresponding "markedly different" standard for modified products of nature, later applied in *Diamond v. Chakrabarty*. The non-analogous structure and function standard properly distinguishes eligible from ineligible applications or modifications of natural discoveries. The standard has a long history dating to the 1793 Patent Act. To avoid further confusion, this Court should clarify its dicta suggesting that merely avoiding preemption or that artificial, human creation alone is sufficient for eligibility. The Court also should clarify that the presence or absence of a non-analogous inventive concept must be determined using a two-way test of the significance of the differences from the ineligible discovery and the other claim limits.

As this Court reiterated in *Bilski v. Kappos* and recognized in *Mayo*, Section 101 codified the rule adopted by this Court in *O'Reilly v. Morse* that treats ineligible natural discoveries as prior art. This rule assures that the claim is properly evaluated to assess whether it reflects an *original* inventive concept. This

Court should state explicitly that such prior art treatment is a Constitutional requirement.

Given the prior art treatment of the discovered natural gene sequences and molecules, the claimed "isolated DNA" molecules at issue clearly are not "markedly different" and are not patent eligible. Structurally, they are at most analogous to natural DNA and mRNA. Isolating the claimed DNA molecules is not (and was not) a creative advance beyond the ineligible scientific discovery. Functionally, new medical and scientific uses of the claimed molecules rely upon analogous, natural processes of sequence binding and replication.

ARGUMENT

I. The Court Should Clarify That An "Inventive Concept" Requires *Non-Analogous (Markedly Different) Creativity* In The Modification Or Application Of Natural Discoveries.

In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012), this Court reiterated that to be a patent eligible *invention*, a claimed application of an ineligible natural discovery[2]

[2] *See, e.g., Bilski v. Kappos,* 130 S.Ct. 3218, 3225 (2010) (" 'laws of nature, physical phenomena, and abstract ideas' " are not patent-eligible inventions) (citations omitted). The exclusions for natural discoveries are not, in fact, "exceptions" to statutory

(Continued on following page)

must reflect an "'inventive concept.'" *Id*. at 1294 (quoting *Parker v. Flook*, 437 U.S. 584, 594 (1978)). The very concept of "invention" requires a *creative*, human advance on prior knowledge or pre-existing nature. *See, e.g*., 1 William C. Robinson, The Law of Patents for Useful Inventions, §§ 77, 78, at 116-17 (Little, Brown 1890) ("*The application of an idea*, not original with the person who applies it, *is not an invention*. . . . The mental faculties involved in the inventive act are the *creative* not the *imitative* faculties. . . . *[S]kill in applying [others' ideas] to practical results; none of these are creation*. . . .) (first and last emphasis added).

Once a discovery of a law of nature has been made, an inventive concept (a creative advance) can occur (if at all) only *in the application* of such a discovery. *See Mayo*, 132 S.Ct. at 1294 ("Still, as the Court has also made clear, to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'"). Similarly, to be a patent eligible invention reflecting an inventive concept, a claimed product *modifying* a discovered product of nature must have "*markedly different* characteristics from any found in nature and . . . the potential for significant

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subject matter. *Id. See In re Alappat*, 33 F.3d 1526, 1553 n.13 (Fed. Cir. 1994) (en banc) (Archer, C.J., dissenting) ("Defining patentable subject matter is the *raison d'être* of § 101.").

utility." *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980) (emphasis added).

Although the Court has used different language to address processes applying scientific discoveries and products modifying natural material discoveries, it has always required that the "inventive concept" reflect more than the mere application of a discovery to a new "field of use," object, or purpose, and more than the "obvious" or "conventional," "token, post-solution" application or modification of a scientific principle or natural material. *See, e.g., Mayo*, 132 S.Ct. at 1301; *Bilski*, 130 S.Ct. at 3231. Novelty and utility of an application or modification alone have never been sufficient to establish an eligible, inventive concept. *See, e.g., Funk Brothers Seed Co. v. Kalo Inoculant C*o., 333 U.S. 127, 130-31 (1948) (Bond "made an new and different composition of non-inhibitive strains which contributed utility and economy to the manufacture and distribution of commercial inoculants. But we think that that aggregation of species fell short of invention within the meaning of the patent statutes.").[3]

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[3] *See* 1 Robinson, *supra,* § 70, at 108 (Little, Brown 1890) ("[T]he novelty and utility of the result of the inventive act [are] *additional* conditions of patentability. The language of our courts might sometimes lead the incautious reader to imagine that the novelty and utility here required were to be taken as the *tests* by which the presence or the absence of the inventive act could always be determined. *Yet such is not the case.*") (emphasis added).

The Court, however, has not been sufficiently clear regarding what is meant by an "inventive concept." The Court in this case should provide the needed further guidance for lower courts, patent examiners, and the public. Such guidance will avoid unnecessary litigation and foregone sequential innovation resulting from improperly granting patents to purported inventions lacking an inventive concept. Such purported inventions add nothing to the "'storehouse of knowledge'" beyond what should be "'free to all men and reserved exclusively to none.'" *Bilski*, 130 S.Ct. at 3225 (quoting *Funk Bros.*, 333 U.S. at 130).

Specifically, the Court should clarify that an "inventive concept" requires a *creative*, *non-analogous* modification or application of an ineligible natural discovery. In other words, the inventive concept must possess a *markedly different* structure *and* function from the ineligible discovery. Otherwise, the claim to the purported invention will effectively protect the discovery itself, even if it does not claim all modifications and applications thereof. *See Mayo*, 132 S.Ct. at 1297 ("If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has *additional features* that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.") (emphasis added).

In 1952, Congress codified in Section 101 this Court's non-analogous structure and function (markedly different) standard for eligibility, which the

Court had long established as the means to avoid such monopolization. Without non-analogous creativity, natural discoveries could be monopolized in small bites (rather than swallowed whole) by claims to narrow but uncreative applications or modifications. The non-analogous structure and function standard also avoids the reductio ad absurdum that patents would never issue to claims applying or modifying natural discoveries. Rather, the standard assures that patents protect *only* the creative human contribution beyond what should be freely available.

Relatedly, the Court should clarify its dicta regarding concerns about "preemption," originating with *Gottschalk v. Benson*, 409 U.S. 63 (1972). *See id*. at 72 ("if the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself"). *See also, e.g., Mayo*, 132 S.Ct. at 1294; *Bilski*, 130 S.Ct. at 3230. These statements can be misconstrued to suggest that merely claiming a limited scope of application or modification of a natural discovery is sufficient for eligibility, even without an inventive concept. The Court also should clarify its dicta originating with *Chakrabarty*, which can be misconstrued to suggest that artificial, human creation alone is sufficient for eligibility. *See* 447 U.S. at 313 ("Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."). *See also, e.g., J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc*., 534 U.S. 124, 130 (2002). Non-preemption and

artificiality are necessary but not sufficient conditions for eligibility. *See, e.g., Funk Bros.*, 333 U.S. at 130-31. Conversely, limiting eligibility to non-analogous applications or modifications of natural discoveries necessarily avoids preemption and assures artificial creation.

The Court also should clarify the method of assessing claims for the presence or absence of a non-analogous inventive concept. Because all inventions are essentially combinations of pre-existing elements, non-analogousness should be determined using a two-way test of the significance of the differences from both the underlying natural discovery and the other claim limitations. *See, e.g., KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418-19 (2007) ("inventions in most, if not all, instances rely upon building blocks . . . and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known."); *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 842 (Fed. Cir. 1991) ("'Virtually all inventions are combinations and virtually all are combinations of old elements.'") (citation omitted). The two-way test assures that the existence of an inventive concept will be properly assessed regardless of the form of the claim.

A. Section 101 Codified This Court's Precedents Requiring a Non-Analogous "Inventive Concept" for Eligibility.

In 1952, Congress made two significant changes to the requirements for patent eligible and patentable

inventions. First, in the only directly relevant change to the law of patent eligibility, Congress overruled dicta from *In re Thuau*, 135 F.2d 344, 347 (C.C.P.A. 1943), which had been construed in later cases to suggest that *no* new *use* of an existing process or thing could constitute an eligible invention. *See, e.g.*, Pasquale J. Federico, *Commentary on the New Patent Act*, 75 J. Pat & Trademark Off. Soc'y 161, 177-78 (1993) (1954) (noting that *Thuau held* only that existing *compositions of matter* could not be considered new inventions and claimed as such simply because a new use for them had been found, "although some of the statements made in the decision are not completely defensible"). Congress did so by adopting in Section 100(b) of the new act a definition of "process," one of the four categories of patent eligible subject matter recited in Section 101 and its predecessors. That definition states that a statutory process "includes a new use of a known process, machine, manufacture, composition of matter, or material." 35 U.S.C. § 100(b).[4]

As the legislative history of Section 100(b) noted, moreover, "[t]he definition of process has been added

[4] To simplify drafting, Congress also provided a definition of invention that includes inventions and discoveries. *See* 35 U.S.C. §§ 100(a), 101. Congress did not thereby intend to alter long-standing eligibility standards. Inclusion of the word "discovery" in the definition does not merit any significance, as the "invented or discovered" language has been in the Patent Act since its inception. *See* Patent Act of 1790, ch. 7, § 1 Stat. 109 (Apr. 10, 1790).

. . . to clarify the present law as to the patentability *of certain types* of *processes or methods* as to which some insubstantial doubts have been expressed." H.R. Rep. No. 82-1923, at 6 (emphasis added). This change was understood at the time to have been *limited to restoring* the Supreme Court's standard for the eligibility of *process* claims for new uses under the 1870 Act, which the lower courts had wrongly limited. Specifically, Congress intended to restore the *non-analogous use* standard this Court had articulated in *Ansonia Brass & Copper Co. v. Electric Supply Co.*, 144 U.S. 11 (1892). *See, e.g.*, Stefan A. Reisenfeld, *The New United States Patent Act in the Light of Comparative Law I*, 102 U. Penn. L. Rev. 291, 299-300 (1954) ("[T]he background of the amendment gives reason to assume that a newly discovered use for a known substance, machine or process is still only patentable *if it is not merely analogous or cognate to the uses heretofore made*.... [I]n essence the new statutory definition of 'process' restores the broad principles of patentability flowing from a careful analysis of the exposition given by the Supreme Court in the *Ansonia* case.") (emphasis added). This was confirmed in *Application of Ducci*, 225 F.2d 683, 688 (C.C. P.A. 1955).

Ansonia Brass had held that "nothing is better settled in this court than that the application of an old process to a *new and analogous purpose does not involve invention*, even if the new result had not before been contemplated." *Id.* at 18 (emphasis added). *See* George T. Curtis, A Treatise on the Law of Patents for Useful Inventions in the United States of

America § 87, at 120 (Little Brown 2d ed. 1854) ("the new occasion or purpose . . . [must] not be merely analogous to the former occasions or purposes"). As discussed below, the Court's non-analogous structure and function standard for determining if an invention exists (and the corresponding "markedly different" standard for products modifying natural phenomena) dates to cases decided under the 1793 Act. Given the long history of that eligibility standard and the contemporaneous understanding to restore it, Section 100(b) should be understood to have codified the non-analogous use standard for *process* claims. *See* H.R. Rep. No. 82-1923, at 1 ("[T]he purpose of the bill is to revise and codify the laws relating to patents. . . ."). To hold otherwise would attribute to the 1952 Congress an intent to repeal centuries of settled doctrine without *any* discussion thereof.

Section 100(b), moreover, has no application whatsoever to *product* claims (machines, manufactures, and compositions of matter). Had Congress in 1952 intended *any* change to the standard for eligibility of products, Congress could have and would have said so (as it did for processes in Section 100(b)). Accordingly, the 1952 Act codified the Court's consistent, earlier interpretations of the relevant requirements for eligibility of products. *See, e.g., Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 185 (1994); *Lorillard v. Pons*, 434 U.S. 575, 580 (1978).

The second, and indirectly relevant, change adopted by Congress in 1952 was to create a new *patentability* standard to address the degree of

creative advance required for *eligible inventions*. Congress created a separate section (Section 103) with new language (obviousness) to determine whether the degree of creative advance reflected by an invention warranted granting a patent. In enacting Section 103, Congress was responding to the uncertainty that had been created regarding the degree of creativity required after *Cuno Engineering Corp. v. Automatic Devices Corp*., 314 U.S. 84 (1941). *See* Federico, *supra*, at 183-84. *See also Graham v. John Deere Co*., 383 U.S. 1, 14-17 (1966) (holding that Congress did *not* change the required degree of creativity when adopting Section 103).

Section 103, however, applies only to *inventions* that are determined to be eligible under Section 101. *See* 35 U.S.C. § 103(a) (2006) ("A patent may not be obtained though *the invention* is not identically disclosed or described as set forth in Section 102") (emphasis added); 35 U.S.C. § 102 (2006). Nothing in Section 103 changed the law regarding what qualifies as an invention in the first instance. *But cf*. Giles S. Rich, *Laying the Ghost of the "Invention" Requirement*, 1 APLA Q.J. 26, 29 (1972-73) ("[F]or the century following *Hotchkiss v. Greenwood*[, 52 U.S. (11 How.) 248 (1851),] we had what was called the 'requirement for invention,' which, I emphasize, we have *not* had for the past twenty years. Instead we have § 103.").

In particular, Congress when adopting Section 103 did not change the eligibility requirements in Section 101 *for claims that modify or apply ineligible discoveries of nature*. As this Court recognized in

Mayo (and as discussed in Section II below), natural discoveries are to be treated as if they were prior art against the applicant when determining if an invention has been made. However, nothing in Section 102 or in Section 103 treats natural discoveries as if they were prior art, or even excludes them from being patented. *See Mayo*, 132 S.Ct. at 1304 ("But §§ 102 and 103 say nothing about treating laws of nature as if they were part of the prior art when applying those sections."). The requirement for prior art treatment of natural discoveries, and thus their ineligibility and the need for an inventive concept in applying or modifying them, remains exclusive to Section 101. For this reason, Section 101 both is critically important and does not duplicate the obviousness standard of Section 103. *See generally* Joshua D. Sarnoff, *Patent Eligible Inventions After* Bilski: *History and Theory*, 63 Hastings L.J. 53, 56-58, 101-10 (2011).

B. The Non-Analogous (Markedly Different) Structure and Function Standard for Determining "Invention" Has Existed Since the 1793 Act.

The non-analogousness standard adopted by the Court in *Ansonia Brass* had a long history, for both products and processes. *See, e.g.*, Sarnoff, *supra*, at 63-84. In the 1793 Act, Congress confirmed the approach adopted by the Patent Board under the 1790 Act, excluding from a patent-eligible "discovery" a "simpl[e] chang[e to the] form or proportions" of

machines or compositions of matter. Patent Act of 1793, ch. 11, § 2, 1 Stat. 318, 321 (Feb. 21, 1793). Under that Act, lower courts first confirmed for American law the exclusion of natural discoveries from the patent system. *See, e.g., Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C. D. Mass. 1817) (No. 8,568) ("It has been often decided, that a patent cannot be legally obtained for a mere philosophical[5] or abstract theory."). *Cf. Boulton v. Bull*, 126 Eng. Rep. 651, 667 (1795) (Lord Eyre, C.J.) (no patents for "mere principle[s]"); *id*. at 663 (Buller, J.) (no patents for "an idea or principle alone"). The lower courts then confirmed that an eligible invention required the creation of a *non-analogous* thing or method (although the existence of an invention was sometimes conflated with the question of its novelty).[6] *See, e.g.*, *Whitney v. Emmitt*, 29 F. Cas. 1074, 1078 (C.C. E.D. Pa. 1831) (No. 17,585) ("if the patent is for [a new manufacture], it must be for something *substantially* new, different from what was before known; if [for a new manner of producing an old manufacture], the mode of operation must be *different*, not a *mere* change of the form and proportions; if both are the same in principle, structure, mode of operation, and produce the same result, they are not new, *though there may*

[5] "Philosophical" was then understood to mean pertaining to the natural sciences. *See, e.g.,* The Compact Edition of the Oxford English Dictionary 180 (Oxford Univ. Press 1971).

[6] *See generally* Edward C. Walterscheid, *Novelty and the* Hotchkiss *Standard,* 20 Fed. Cir. B.J. 219, 227-28 (2010) (discussing "substantial novelty" and citing cases).

be a variance in some small matter for the purpose of evasion") (emphasis added).

In the 1836 Patent Act, Congress removed the statutory language regarding changes to form and proportions. *See* Patent Act of 1836, ch. 357, § 6, 5 Stat. 117, 119 (July 4, 1836). Nevertheless, under that Act, this Court reconfirmed in *Le Roy v. Tatham*, 55 U.S. (14 How.) 156 (1853), that natural discoveries are excluded from patent eligibility. *See id*. at 175 ("no one can claim in . . . [principles in the abstract] an exclusive right."). The Court then explained in *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1854) – relying on the English precedent of *Nielson v. Harford*, 151 Eng. Rep. 1266 (1841) – that such natural discoveries are to be treated as *if they were prior art* (not as inventions of their discoverers) when evaluating the existence (or not) of an invention. *See* 56 U.S. (15 How.) at 116 (in *Nielson* "it was finally decided that this [discovered] principle [of physical science that hot air will promote fuel ignition better than cold] *must be regarded as well known*, and that the plaintiff had invented a mechanical mode of applying it to furnaces . . . [T]he court emphatically denied this [argued] right to such a patent [for the natural discovery itself]."") (emphasis added). Finally, this Court and lower courts continued to require non-analogous new things or new uses for an invention to exist. *See, e.g*., *Le Roy*, 55 U.S. at 175, 177 ("the invention is not in discovering the[elements of the power], but in applying them to useful objects. . . . 'If it is old and well known, *and applied only to a new purpose*, that

does not make it patentable.'") (quoting *Bean v. Smallwood*, 2 F. Cas. 1142 (C.C. D. Mass. 1843) (No. 1,173)) (emphasis added); *Howe v. Abbott*, 12 F. Cas. 656, 658 (C.C. D. Mass. 1842) (No. 6,766) ("The application of an old process to manufacture an article, *to which it had never before been applied*, *is not* a patentable *invention*.") (emphasis added).

In the 1870 Act, Congress did not make any relevant change to the eligibility requirements, preserving the Court's interpretations of the limits of an eligible "invention." *See* Patent Act of 1870, ch. 230, § 24, 16 Stat. 200 (July 8, 1870). Shortly before *Ansonia Brass*, the Court reiterated in *The Telephone Cases* that more than mere application of a natural discovery to a new use was required for eligibility. *See Dolbear v. American Bell Telephone Co.*, 126 U.S. 1, 534 (1888) ("In the present case the claim is not for the use of a current of electricity in its natural state as it comes from the battery . . . but for putting a continuous current, in a closed circuit, into a certain specified condition. . . ."). Similarly, as stated by the Court of Appeals in *Wall v. Leck*, 66 F. 552 (9th Cir. 1895):

> [E]mployment of [a scientific discovery] in the modes or through the instrumentalities by which it is applied in nature is a mere limitation of what every man is able to perceive and reproduce as well as [t]he [patentee]. All endeavors to confine it to himself are at once futile and unjust. . . . Not until some new instrument or method is contrived for its

> direction *towards ends which it cannot naturally accomplish* does his creative genius manifest itself.

Id. at 558 (citing 1 Robinson, *supra*, § 136) (emphasis added).

Although this Court when addressing modified products of nature ("natural phenomena" or "physical phenomena"[7]) used different terminology, it also required for invention a non-analogous structure and function. For example, in *Hartranft v. Wiegmann*, 121 U.S. 609 (1887), the Court held that to qualify as a manufacture required "a new and different article, having a *distinctive* name, character, or use. . . . The application of labor to an article, either by hand or by mechanism, does not make the article necessarily a manufactured article. . . ." *Id*. at 615. Similarly, in *American Fruit Growers, Inc. v. Brogdex Co*., 283 U.S. 1 (1931), the Court addressed a novel and useful (but structurally and functionally analogous) borax-treated preserved fruit. The Court held that for invention to exist "a new *and different* article must emerge." *Id*. at 13 (emphasis added). Given the known preservative functions of borax and the food function of fruit, making the novel and useful structural combination was not an invention. *See id*. at 14.

As the Commissioner of the Patent Office (and one of the principal drafters of the 1952 Patent Act)

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[7] *See, e.g., Mayo,* 132 S.Ct. at 1293 (citations omitted); *Bilski,* 130 S.Ct. at 3225 (citations omitted).

recognized shortly after *American Fruit Growers*, some patents had been improperly issued under the 1870 Act (such as Pasteur's yeast patent) for isolated or purified natural products that lacked the requisite marked differences of structure and function. *See* Pasquale J. Federico, *Louis Pasteur's Patents*, 86 Science 327 (October 8, 1937) ("A claim of this type would now probably be refused by the examiner, since it may now be doubted that the subject-matter is capable of being patented.").[8]

Just prior to the 1952 Act, moreover, this Court reaffirmed that invention required a creative, non-analogous inventive concept, not merely novelty and utility. The bacterial cultures at issue in *Funk Brothers* were both structurally novel (as they had not previously been combined) and had valuable new uses (because of the natural discovery of the non-inhibition

[8] The comparison to the instant case is apt, although the magnitude of the granting errors is much greater in regard to gene patents. Further, isolated and purified natural products may become eligible *if* they have become non-analogous things. *Cf. Parke-Davis & Co. v. H. K. Mulford Co.,* 189 F. 95, 103 (S.D.N.Y. 1911) (finding isolated and purified adrenaline to be a change of kind rather than of degree from the natural substance, but adopting unfortunate dicta that "even if it were merely an extracted product without change, there is no rule that such products are not patentable"), *aff'd in part*, *rev'd in part*, 196 F. 496 (2d Cir. 1912)); Jon M. Harkness, *Dicta on Adrenalin(e): Myriad Problems With Learned Hand's Product of Nature Pronouncements in* Parke-Davis v. Mulford, 93 J. Pat. & Trademark Off. Soc'y 363, 389-92 (2011) (noting Judge Hand's lack of attention to the product of nature issue given the case focus on novelty).

property of the strains). Nevertheless, the Court held the combination to lack the required inventive concept beyond merely applying the new discovery. *See Funk Bros.*, 333 U.S. at 131 ("The aggregation of select strains of the several species into one product is an application of that newly-discovered natural principle. But however ingenious the [scientific] discovery of that natural principle may have been, *the application of it is hardly more than an advance in the packaging* of the inoculants.") (emphasis added). *Cf. Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939) ("We assume, without deciding the point, that this advance was *invention* even though it was achieved by the logical application of a known scientific law to a familiar type of antenna.") (emphasis added).

C. The Court Should Clarify Its Dicta Suggesting that Merely Avoiding Preemption or Artificial, Human Creation Is Sufficient for Eligibility.

As the Court recently noted in *Mayo*, its precedents establish three concerns. First, eligibility requires a claimed process applying a natural law to reflect an inventive concept that "in practice amounts to significantly more than a patent on the natural law itself." 132 S.Ct. at 1294 (citations omitted). Second, eligibility should not "'depend simply on the draftsman's art' without reference to the 'principles underlying the prohibition against patents for [natural

laws].'" *Id*. (citation omitted). Third, courts should not "uphold[ ] patents that claim processes that too broadly preempt the use of a natural law." *Id*. The first concern is met by the non-analogous (markedly different) structure and function standard. The second concern is met by proper implementation of that standard, which requires both prior art treatment of ineligible discoveries and a two-way test of the significance of the differences from the prior art (as discussed below). However, the Court's third concern can lead to significant confusion.

The lack of *inventive creativity* and scope of *preemption* are entirely different concerns, and only the former is relevant for eligibility determinations. *See, e.g*., Katherine J. Strandburg, *Much Ado About Preemption*, 50 Hous. L. Rev. 563, 564-67 (2012) (discussing use of "preemption" as a measure of the effects of claims on downstream innovation; noting that most of the Court's eligibility decisions turn not on overbreadth but on whether the "application of per se unpatentable elements is sufficiently inventive to traverse the boundary between unpatentable and patentable terrain"). The Court's dicta, unfortunately, have sometimes conflated these two concerns. *See, e.g., Mayo*, 132 S.Ct. at 1301 ("the claim [in *Benson*] (like the claims before us) was overly broad; it did not differ significantly from a claim that just said 'apply the algorithm.' ").

The Court thus should clarify that its concern about preemption of innovation *is not a test for*

determining eligibility of claims applying or modifying ineligible natural discoveries. Rather, preemption was one of the historical motivating reasons for finding natural discoveries *to be ineligible in the first instance*. *See* Sarnoff, *supra*, at 85-90 (tracing religious concerns over patenting "God's work" that corresponded with utilitarian views that private ownership of natural discoveries would be bad innovation policy). As this Court held in *The Telephone Cases*, *if* an eligible, inventive concept is present in a claim applying a natural discovery, *then* the claim can preempt the entire scope of application of that concept (not of the discovery).[9] *See Dolbear*, 126 U.S. at 534-35 ("It may be that . . . practically, [Bell's] patent gives him its exclusive use for [transmitting speech by electricity], but that does not make his claim one for the use of electricity distinct from the particular process. . . . It will, if true, show more clearly the great importance of his [creative human] discovery, but it will not invalidate his patent."). A creative invention, just like a law of nature, may be either broad or narrow; a claim to the former may preempt

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[9] *See, e.g.,* 1 Robinson, *supra,* § 81, at 124 & n.3 ("The law regards him as the owner of the invention for any and every purpose to which it can be applied, and thus secures to him the entire benefit of his original idea. . . . [This] doctrine is, therefore, limited to such benefits *as the inventive skill of the inventor in question has actually conferred upon the public*. . . .") (emphasis added). The scope of application of *inventions* is currently limited only by the reverse doctrine of equivalents. *See Westinghouse v. Boyden Power Brake Co.,* 170 U.S. 537, 571, 573 (1898).

its full scope, while a claim to the latter is simply ineligible. *Cf. Mayo*, 132 S.Ct. at 1303.[10]

The Court's dicta, moreover, can easily be misconstrued to suggest that merely avoiding preemption of a natural discovery is sufficient for eligibility. For example, if avoiding preemption of all uses of Einstein's discovery were sufficient for eligibility, the hypothetical claim discussed in *Mayo should* be eligible. *See* 132 S.Ct. at 1297 (instructing linear accelerators to refer to Einstein's mass-energy conversion law to determine "how much energy an amount of mass has produced (or vice-versa)."). That is because use in linear accelerators to determine mass-energy conversions would be only one, very small subset of applications of Einstein's law, employing a specific, complex machine to achieve a new, particular, and

[10] To the extent the Court remains concerned over the effects on downstream innovation of granting broad patents for eligible inventions, it may wish to revisit in an appropriate case the recent radical restriction of the scope of the experimental use "exception" to infringement. *See, e.g., Roche Prods. Inc. v. Bolar Pharms.,* 733 F.2d 858 (Fed. Cir. 1984); *Madey v. Duke Univ.,* 307 F.3d 1351 (Fed. Cir. 2002). *Cf. Proveris Scientific Corp v. InnovaSystems, Inc.,* 536 F.3d 1256 (Fed. Cir. 2008). Historically, that doctrine prevented research on *and with* patented inventions from being considered infringing acts, permitting unrestricted, further discovery, invention, and innovation. *See generally* Henrik Holzapfel & Joshua D. Sarnoff, *A Cross-Atlantic Dialog on Experimental Use and Research Tools*, 48 IDEA 123, 133-44 (2008) (discussing the history of the doctrine).

valuable use.[11] Rather, the reason such a claim is ineligible is that the use claimed is directly analogous to the natural discovery, and thus there is no creative inventive concept in that application.

Similarly, the ineligible claim actually at issue in *Mayo* would not have become eligible simply by avoiding preemption of all (or most) uses of the discovered correlation. For example, it would add no creativity to limit the claim to the conventional treatment step of actually adjusting the dose of the synthetic drugs administered, but the claim may routinely be practiced without that added step (*e.g.*, in diagnosis, for further study, etc.). *Cf. id*. at 1298 ("the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients."). *But cf. id*. at 1303 ("the patent claims do not confine their reach to particular applications of those laws.").

Clarifying that preemption is not directly relevant to determining eligibility will discourage claim drafting efforts seeking to limit the scope of application of natural discoveries without adding creativity, in an effort to evade this Court's historic limits on eligibility codified by Section 101. *Cf. Mayo*, 132 S.Ct. at 1297 ("the 'prohibition against patenting abstract ideas "cannot be circumvented by attempting to limit

[11] The example demonstrates that this Court properly rejected the "machine-or-transformation" approach as a *test* of eligibility in *Bilski*. *See* 130 S.Ct. at 3226-27.

the use of the formula to a particular technological environment."'") (citations omitted); *id*. at 1300 ("'"*Flook* established that . . . adding token post-solution components did not make the concept patentable."'") (citations omitted). It will thereby also avoid unnecessary litigation over patents that lack an inventive concept but monopolize only some, not all, of the ineligible discovery itself.

Similarly, this Court should clarify that its dicta distinguishing artificial, human creations from discovered products of nature state a necessary but not a sufficient condition for eligibility. *See Chakrabarty*, 447 U.S. at 313 ("human-made inventions."). Again, this dicta could readily be misconstrued to suggest that mere artificial, human applications or modifications of natural discoveries are eligible. Were mere artificiality sufficient, many of this Court's precedents could not be justified. For example, in *Mayo*, the thiopurine drugs administered as part of the claims were synthetic human creations, and as the Court noted "[w]hile it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action." 132 S.Ct. at 1297. The treated fruit in *American Fruit Growers* and the combined bacterial strains in *Funk Brothers* were artificial, human creations. So was synthetic alizarine, which the Court expressly held in *Cochrane v. Badische Analin & Soda Fabrik*, 111 U.S. 293 (1884), was not an eligible invention merely because claimed as an artificial

preparation. *See id.* at 311 ("Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially") (citing *American Wood Paper Co. v. The Fibre Disintegrating Co.*, 90 U.S. (23 Wall.) 566, 593 (1874)).

The Court thus should clarify that inventions must not only be "human-made," but also markedly different from natural products. As with clarifying preemption dicta, the Court will help to avoid further improper patent grants, further efforts to evade eligibility limits, and further unnecessary litigation.

D. The Court Should Adopt a Two-Way Test of the Significance of the Differences from the Natural Discovery.

Although this Court's dicta have sometimes conflated the questions of whether an inventive concept is present and whether preemption exists, the Court has properly looked for an inventive concept from both perspectives of the claimed combinations: how do the additional elements of the claim creatively apply or modify an ineligible natural discovery; and what does the discovery add to an existing product or process. For example, as the Court discussed in *Mayo*, *Flook* involved an ineligible claim combining an ineligible mathematical equation (treated as if it were prior art) with a known process for catalytic conversion of hydrocarbons. *See* 132 S.Ct. at 1299. The Court in *Flook* sought to determine eligibility *first* by

noting that the claim did not provide any guidance regarding how the elements of the process worked with the ineligible formula (and thus "did not limit the claim to a particular application" of the discovery), and *second* by analyzing the nature of the process limitations added to the ineligible formula (which were "'well known' to the point where, putting the formula to the side, there was no 'inventive concept'"). *Id*. (*quoting Flook*, 437 U.S. at 594).

This two-way analysis of non-analogousness is the proper approach. The structures and functions *identified in nature* may not by themselves suggest combination with an existing process or product, but that process or product may itself suggest the combination when the natural discovery is similar to existing structures and functions already employed. For example, the Pythagorean theorem by itself may not have been applied in architecture prior to its discovery, and thus its discovery may not have suggested combination with rulers and compasses to make diagrams. But given prior calculations to make diagrams, substituting the theorem (once discovered and treated as prior art) would have been directly analogous (even if novel and highly useful) to existing architectural processes. No inventive concept would exist in claiming the theorem's use for this purpose.

Similarly, as this Court also discussed in *Mayo*, the claimed process in *Diamond v. Diehr*, 450 U.S. 175 (1981), was found eligible

> because *of the way the additional steps of the process integrated the equation into the process as a whole*. . . . [The Court] nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional. . . . These other steps *apparently added to the formula something that* in terms of patent law's objectives *had significance* – they transformed the process into an inventive application of the formula.

132 S.Ct. at 1298-99 (emphasis added).[12] Again, the Court applied a two-way analysis for a non-analogous inventive concept: adding the discovery to something and the other way around. One-way non-analogousness is not enough.

The two-way test for an inventive concept makes eminent sense, given prior-art treatment of ineligible discoveries. Either the discoveries or the elements they are combined with may suggest making a claimed combination (as may extrinsic motivations, alternative problems, or ordinary human practices). *See, e.g., KSR Int'l*, 550 U.S. at 418-22. The two-way analysis, moreover, should make it easier to determine the presence or absence of an inventive concept

[12] This holding, however, was highly questionable given that similar rubber curing processes not continuously monitoring temperature, but using the same equation, had been in use. *See* 450 U.S. at 179. The Court would assist understanding and avoid untold future litigation if it simply acknowledged here that *Diehr* was wrongly decided.

regardless of the form of the claim as a process or as a product (machine or system, manufacture, or composition of matter). In all cases, the question will be what the functional or structural claim limits *creatively* add to the natural discovery and what the ineligible discovery *creatively* adds to prior art processes or things. So long as the two-way test of non-analogousness is employed, the Court can leave for further judicial and administrative development the requisite *degree* of creative advance that will establish non-analogousness in particular cases.

II. The Court Should Reaffirm That Ineligible Discoveries Must Be Treated As Prior Art When Evaluating The Presence Or Absence Of An Inventive Concept.

In *Bilski*, the Court reiterated language originating in *O'Reilly* that natural discoveries must be treated as if they were prior art for eligibility. "The Court concluded [in *Flook*] that the process at issue there was 'unpatentable under § 101, not because it contain[ed] a mathematical algorithm as one component, but because once that algorithm [wa]s *assumed to be within the prior art*, the application, considered as a whole, contain[ed] no patentable *invention*.'" *Id*. at 3230 (quoting *Flook*, 437 U.S. at 594) (emphasis added). *See Flook*, 437 U.S. at 595 ("If we assume that that method was also known, as we must under the reasoning in *Morse*"); *O'Reilly*, 56 U.S. (15 How.) at 115-16. The Court, however, has failed to emphasize the significance of prior art treatment or to

explain why it is needed for determining whether an inventive concept exists. It should do so here.

A. Without Prior Art Treatment, Any Claimed Modification or Application of an Ineligible Discovery Can Masquerade As an Inventive Concept.

Although "the discovery of . . . a [natural] phenomenon cannot support a patent," it is prior art treatment of ineligible discoveries that mandates that "there [be] some *other inventive concept* in [their] application." *Flook*, 347 U.S. at 594 (emphasis added). This is true even when considering a claimed invention "as a whole." *Id*. Otherwise, the creative advance of the discovery itself may be improperly viewed as the "inventive concept" of any claim that modifies or applies it. *See, e.g., Diehr*, 450 U.S. at 192 ("To hold otherwise would allow a competent draftsman to evade the recognized limitations on the type of subject matter eligible. . . ."); *Alappat*, 33 F.3d at 1554 (Archer, C.J., dissenting) ("The discovery of music does not become patentable subject matter simply because there is an arbitrary claim to some structure."). This is because it may take creativity to *discover* the ineligible product of nature or scientific principle but not to *combine* it (once known) with the existing art.

For example, without prior art treatment, substituting a new algorithm for analogous timing calculations in a hydrocarbon cracking process might appear

to be an inventive concept, even if the only creative advance were in the ineligible algorithm. Conversely, adding the cracking process to the algorithm might appear to be a creative advance without prior art treatment, particularly if the algorithm was not discovered in (and thus did not suggest its use in) the context of cracking. By treating the ineligible discovery as prior art, both the algorithm and its properties will already be taken into account when assessing whether its substitution into an existing process is a creative, non-analogous advance.

B. The Court Should Explicitly Hold That Prior Art Treatment Is a Constitutional Requirement.

Prior art treatment of ineligible discoveries is no mere historical accident. Through the late 18th century, "invention" had a technical meaning that distinguished it from discoveries of scientific principles, natural phenomena, and fundamental information (as well as from discoveries of exploration or in the liberal and fine arts).[13] Science, nature, and abstract ideas were thought to originate from God. Accordingly, natural discoveries were not thought to be human

[13] *See, e.g.,* Edward C. Walterscheid, The Nature of the Intellectual Property Clause: A Study in Historical Perspective 365-66, 375-76 (William S. Hein & Co. 2002) (hereinafter "Walterscheid, *Study*")); John R. Thomas, *The Patenting of the Liberal Professions,* 40 B.C. L. Rev. 1139, 1164-65 (1999).

creations that were the proper objects of exclusive private property rights.[14]

Further, scientists who made such discoveries were thought to owe moral duties to share their discoveries freely with the public, which was then entitled to benefit from the information. As Lord Camden stated in 1774, scientists are "intrusted by Providence with the delegated power of imparting to their fellow-creatures that instruction which heaven meant for universal benefit; they must not be niggards to the world, or hoard up for themselves the common stock." 17 The Parliamentary History of England col. 999 (William Cobbett ed., 1806-20) (1774). This perceived moral duty of scientists – which corresponded with utilitarian beliefs of the social benefits of protecting the public domain – historically grounded the prior art treatment of natural discoveries.[15]

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[14] *See* Christine MacLeod, Inventing the Industrial Revolution: The English Patent System 1660-1800, at 198-203 (Cambridge Univ. Press 2002) (1988); Walterscheid, *Study, supra*, at 39, 375-76. *Cf. Feist Publ'ns, Inc. v. Rural Tele. Serv. Co.,* 499 U.S. 340, 347 (1991) (distinguishing "discovery" from "creation"; holding that facts cannot be original creations of their discoverers); Letter from Thomas Jefferson to Isaac MacPherson (Aug. 13, 1813), *in* Thomas Jefferson, The Portable Thomas Jefferson 525, at 529-30 (Merrill D. Peterson ed., Penguin Books 1977) (explaining why ideas are not subject to property rights).

[15] *See* 1 *Robinson*, *supra,* § 25, at 39 ("To benefit by the discoveries of his fellow-men is thus not only a natural right, it is also the natural duty which every man owes to himself and to society; and the mutual, universal progress thence resulting is the fulfillment of the earthly destiny of the human race."). *See generally* Sarnoff, *supra,* at 84-90.

Otherwise, as noted above, claims to uncreative applications would be able to partially monopolize natural discoveries. *Cf. Mayo*, 132 S.Ct. at 1293 ("monopolization of those [basic] tools [of scientific and technological work] through the grant of a patent might tend to impede innovation more than it would tend to promote it").

This history is reflected in the Constitution's language and purpose. As this Court has recognized, the Constitution requires *originality* for copyrights and patents, given authorization of exclusive rights only for "Authors and Inventors to their respective . . . Writings and Discoveries." U.S. Const., art. I, § 8, cl. 8.[16] An original "Discovery" of an "Inventor" in the constitutional sense requires *invention*, which in turn requires a *creative* human advance *beyond* any new natural discovery. *See, e.g., Kewanee Oil Co. v. Bicron Corp*., 416 U.S. 470, 476 (1974) ("discovery is something less than invention"); *In re Kemper*, 14 F. Cas. 286, 287 (C.C. D. D.C. 1841) (No. 7,687) ("A discovery, in this sense, is not the subject of a patent" but as used in the Constitution is always "synonymous with invention."); Rich, *supra*, at 29-34 (a qualitative

[16] *See Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.,* 499 U.S. 340, 346 (1991) ("Originality is a constitutional requirement. . . . [In *The Trade-Mark Cases,* t]he Court explained that originality requires independent creation *plus a modicum of creativity*. . . . [In *Burrow-Giles,*] the Court emphasized the *creative* component of originality.") (citing *In re Trade-Mark Cases,* 100 U.S. 82, 94 (1879), and *Burrow-Giles Lithographic Co. v. Sarony,* 111 U.S. 53, 58 (1884)) (emphasis added).

"invention" requirement is reflected in the Constitution's restriction to "Inventors"); Albert H. Walker, Text-book of the Patent Laws of the United States of America 2 (2d ed. 1889) ("The word 'discovery' . . . in the Constitution. . . . means invention . . . and . . . nothing else."). *Cf. Mazer v. Stein*, 347 U.S. 201, 220-21 (1954) (Douglas, J., concurring) ("Perhaps these are all 'writings' in the constitutional sense. But to me, at least, they are not obviously so. It is time that we came to the problem full face."). *See generally* Oskar Liivak, *The Forgotten Originality Requirement: A Constitutional Hurdle for Gene Patents*, 87 J. Pat. & Trademark Off. Soc'y 261, 273-75 (2005).

Without reflecting an inventive concept that goes beyond (is not analogous to) an ineligible discovery, a claimed product or process will lack originality under the Constitution. Prior art treatment assures that uncreative applications or modifications of natural discoveries are not considered original inventions. No matter how much effort or creativity may have gone into identifying natural discoveries, the discoveries themselves and analogous applications or modifications of them simply are not within the constitutional grant of power. *Cf. Morton v. New York Eye Infirmary*, 17 F. Cas. 879, 884 (C.C. S.D.N.Y. 1862) (No. 9,865) ("'A discovery may be brilliant and useful, and not patentable. . . . The new force or principle brought to light . . . can be patented *only* in connection *or combination* with the means by which, or the medium through which, it operates.'") (emphasis added).

The Court in this case should expressly hold that prior art treatment of ineligible discoveries is a constitutional requirement. Without such a clear statement of the Constitution's limits, foreseeable lobbying may induce Congress to seek to validate retroactively (to a decision in this case) the thousands of ineligible gene patents that have issued.

III. The Claimed Isolated DNA Molecules Are Ineligible, As Their Structure And Functions Are At Most Analogous To Natural DNA And mRNA.

Given prior art treatment of natural discoveries, the claims at issue for isolated DNA molecules (and thousands of other patents' claims for isolated and/or purified DNA) are clearly ineligible. The claimed molecules do not possess non-analogous (markedly different) structures or functions from the discovered, naturally occurring materials. For example, some of the claims at issue are drawn to "isolated DNA" molecules having a sequence "coding for a *BRCA*1 polypeptide" (a protein) or containing "at least 15 nucleotides" (DNA bases) of that sequence. U.S. Patent No. 5,747,282, cl. 1, 5. The discovered *BRCA*1 gene and its location on the chromosome, the discovered natural chromosomal DNA and mRNA molecules, and the discovered natural chromosomal DNA and corresponding mRNA sequences all must be treated as prior art when evaluating whether the claimed "isolated DNA" molecules are inventions. It should be immediately apparent – however the claims

are construed – that the claimed isolated DNA molecules do not have *markedly different* (non-analogous) structures from the natural DNA and mRNA on which they are based.[17]

It is precisely the identity of the claimed molecules' sequences to those of the discovered DNA and corresponding mRNA that makes such isolated DNA useful and valuable. The sequence identity clearly makes the claimed DNA molecules structurally *analogous* to the discovered natural chromosomal DNA and corresponding mRNA. This is true even if the claim term "isolated DNA" is construed – beyond the words themselves – to require minor differences in chemical structure (such as methylation) from naturally occurring DNA.[18] Similarly, even if the claim term "isolated DNA" is construed to require synthetically created molecules,[19] it would not make the claimed molecules *markedly different*. As noted above in regard to *Cochrane*, artificial production

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[17] All of the claimed fifteen-nucleotide DNA sequences will exist in chromosomal DNA without removing introns (although the chromosomal DNA sequences may not be "isolated" from the surrounding sequences). Similarly, the identified protein-coding sequences (with introns removed) will naturally exist in mRNA, which is not DNA but is subject to the genetic code.

[18] *See generally* J. Sambrook et al., Molecular Cloning: A Laboratory Manual (2d ed. 1989).

[19] Claims unlike those at issue here that are expressly limited to "cDNA" also will be ineligible, whether or not the term "cDNA" is construed to require synthetic production, precluding application to naturally occurring molecules.

alone is not sufficient for eligibility. This should be particularly true when artificial production merely reproduces the discovered natural molecules. *See, e.g.*, Liivak, *supra*, at 282-90.

In fact, the claimed "isolated DNA" molecules (even if synthetically produced) may be structurally *identical* to natural materials. Because of natural viral transcription, both protein-coding-sequence and 15-base-pair-sequence molecules *may* exist in nature separated from the chromosomal DNA material. Further, the claimed isolated DNA molecules may be identical even if chemically modified, given that chemical modification also *may* occur naturally (although statistically may not *always* occur in the same locations).[20]

It should also be apparent that "isolating" the specified DNA molecules is *not* a creative, non-analogous inventive concept. Once the gene's location and the chromosomal DNA and corresponding mRNA molecules and sequences have been identified, determined, and treated as prior art, isolating and synthetically producing the relevant DNA molecules is (and was at the relevant time) a wholly routine and conventional action.[21] The claimed DNA

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[20] *See, e.g.,* Yingying Zhang & Albert Jeltsch, *The Application of Next Generation Sequencing in DNA Methylation Analysis,* Genes 85, 86 (2010).

[21] *See, e.g.,* Sambrook, et al., *supra.* Further, both separation from chromosomes and synthetic production of the relevant sequences may occur in the very process of the scientific discovery

(Continued on following page)

molecules at issue thus are not like the claimed bacteria at issue in *Chakrabarty*, which reflected a non-analogous combination (at least at the time).[22]

Nor are the functions of the claimed, isolated DNA molecules markedly different from (not analogous to) those of the natural DNA on which they are based. The medical uses of the claimed isolated DNA molecules as diagnostics, and the scientific uses of them as probes or primers, depend upon and are directly analogous to the natural functions performed by chromosomal DNA and corresponding mRNA. These natural functions include the chemical and biological processes of homologous sequence binding and sequence replication.[23] These functions are not inventive concepts, even if they are novel and valuable analogous applications of the natural discoveries. These functions depend on the natural discoveries at

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of the gene sequence, demonstrating the lack of creative advance beyond the discovery. *See, e.g.,* Brief of Amicus Curiae Law Professor Christopher M. Holman in Support of Neither Party, *Association for Molecular Pathology v. U.S. Patent and Trademark Office,* 689 F.3d 1303 (Fed. Cir. 2012), at 6-7.

[22] In *Chakrabarty,* the Court focused on the question of whether Congress had prohibited claims to living organisms, not on the question of invention itself. *See* 447 U.S. at 310-18. Nevertheless, the Court distinguished the combination in *Funk Brothers* by noting the markedly different character of the combination at issue, and held its decision was consistent with *Flook. See id.* at 310, 315. The Court did not reach the eligibility of a claim to a more analogous, purified natural product, as the issue had been mooted. *See id.* at 306-07.

[23] *See generally* Sambrook, et al*., supra*.

least as much as the discovered mutual inhibition properties of the combined bacterial strains in *Funk Brothers* and the discovered food preserving function of borax and edible nature of fruit in *American Fruit Growers*.

CONCLUSION

For the foregoing reasons, the Court should affirm the District Court's rejection of the patent claims at issue, adopt the non-analogous structure and function (marked differences) test of an inventive concept, and hold that prior art treatment of ineligible discoveries is a constitutional requirement.

Respectfully submitted,

JOSHUA D. SARNOFF
Counsel of Record for Amici Curiae
DEPAUL UNIVERSITY
COLLEGE OF LAW
25 E. Jackson
Chicago, IL 60604
(312) 362-6326
jsarnoff@depaul.edu

APPENDIX

LIST OF *AMICI CURIAE*
LAW PROFESSORS[1]

Margo Bagley
Professor of Law
University of Virginia School of Law

Dr. Irene Calboli
Professor of Law
Marquette University Law School

Andrew Chin
Associate Professor of Law
University of North Carolina School of Law

Jorge L. Contreras
Associate Professor
American University Washington College of Law

Llewellyn Joseph Gibbons
Associate Professor of Law
University of Toledo College of Law

Herbert Hovenkamp
Ben V. & Dorothy Willie Professor
University of Iowa College of Law

William Hubbard
Assistant Professor of Law
University of Baltimore School of Law

Jennifer Carter-Johnson, Ph.D., J.D.
Assistant Professor of Law
Michigan State University College of Law

[1] Affiliations provided for identification purposes only.

Yvette Joy Liebesman
Assistant Professor
Saint Louis University School of Law

Charles R. McManis
Thomas & Karole Green Professor of Law
Washington University School of Law

Lateef Mtima
Professor of Law and Director,
Institute for Intellectual Property and Social Justice
Howard University School of Law

Luigi Palombi
Former Adjunct Professor of Law
The University of Sydney

Joshua D. Sarnoff
Professor of Law
DePaul University College of Law

Lea Shaver
Associate Professor
Indiana University Robert H. McKinney School of Law

Arthur Tan-Chi Yuan
Adjunct Professor,
Director, Chinese IP Resource Center &
Director, Patent Clinic
The John Marshall Law School