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 *AMICUS CURIAE* OF PROFESSOR JEFFREY A. LEFSTIN IN SUPPORT OF RESPONDENTS

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## I. INTEREST OF *AMICUS CURIAE*[1]

*Amicus* is a Professor of Law specializing in patent law, with a particular focus on the history of patent law and its institutions. *Amicus* also holds a Ph.D. in biochemistry and molecular biology. *Amicus*'s interest in this case lies solely in furthering the development of patent law. *Amicus* submits this brief to assist this Court, in light of historical experience, in selecting the appropriate analytical framework for subject matter eligibility under 35 U.S.C. § 101.

## II. SUMMARY OF ARGUMENT

In *Mayo v. Prometheus*,[2] this Court suggested, among other approaches, that claims lack patent-eligibility unless they represent inventive applications of laws of nature and natural phenomena. This analysis appears to revive the framework set forth in *Funk Brothers v. Kalo Inoculant*.[3] Historically, the *Funk* analysis was employed to invalidate a wide variety of seemingly meritorious claims, indicating the Court should proceed with caution before endorsing its

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[1] The parties have consented to the filing of this brief. Pursuant to Rule 37.6 of this Court, amicus curiae certifies that no counsel for any party authored this brief in whole or in part, that no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amicus curiae, its members, and its counsel made such a monetary contribution to its preparation or submission.

[2] 132 S. Ct. 1289 (2012).

[3] 333 U.S. 127 (1948).

analysis. Historical precedents further clarify that the test of patent-eligibility is not whether a claim implements an inventive application of a fundamental principle, but whether a claim is drawn to a fundamental principle unbounded by the patentee's mode of application. Under the latter analysis, isolated and purified DNA molecules derived from human genes are patent-eligible subject matter.

## III. ARGUMENT

### A. Introduction.

In *eBay v. MercExchange* the Chief Justice, quoting Justice Holmes, observed that "'a page of history is worth a volume of logic.'"[4] *Amicus*, whose research involves the history of patent law and its institutions, is prompted by the Chief Justice's observation to provide the Court with this historical perspective. In particular, given the past experience of the lower courts applying this Court's standards of subject matter eligibility, *Amicus* hopes to highlight the possible consequences of the Court's interpretation of *Mayo* in this case.

This case appears to be governed by *Mayo*, rather than by this Court's decision in *Diamond v. Chakrabarty*.[5] The issue before the Court in

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[4] 547 U.S. 388, 395 (2006) (quoting *New York Trust Co. v. Eisner*, 256 U.S. 345, 349 (1921)).

[5] 447 U.S. 303 (1980). *Amicus* notes that *Chakrabarty*'s "standard" of "distinctive name, character, and use" derives ultimately from what is now termed the "substantial transformation" test of

*Chakrabarty* was whether claims drawn to living organisms were patent-eligible – not whether Chakrabarty's genetically engineered bacteria were products of nature or natural phenomena. While Chakrabarty's claims were initially rejected by the Patent Office as "products of nature," that rejection was not sustained by the Patent Office Board of Appeals[6] and was not before this Court.[7] Accordingly, the precedent most relevant to this case is this Court's decision in *Mayo*.

In *Mayo* this Court appeared to set forth three possible approaches to determine whether a claim impermissibly attempts to monopolize a fundamental principle, such as an abstract idea, a law of nature, or a natural phenomenon. First, the Court indicated that a claim is not patent-eligible if it amounts to nothing more than an instruction to apply the fundamental principle.[8] Second, the Court indicated that a claim effectively pre-empting all use of a fundamental

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Customs law. *See Am. Fruit Growers v. Brogdex Co.*, 283 U.S. 1, 12-13 (1931) (looking to Customs cases to define "manufacture" as used in patent statute).

[6] *See Chakrabarty*, 447 U.S. at 306 n.3.

[7] The Court's discussion of the "product of nature" doctrine seems to have been prompted by the appellee's mention of *Funk* in his brief. The appellee had argued that if living things were not patent-eligible, this Court would have said so in *Funk*.

[8] *See Mayo*, 132 S. Ct. at 1297, 1301.

principle does not recite patent-eligible subject matter.[9] And third, the Court indicated that a claim is not patent-eligible if it represents a merely conventional or obvious application of a fundamental principle, adding nothing more than routine and well-understood steps to the underlying discovery.[10]

It is the last aspect of *Mayo* that prompts this brief. If *Mayo* is read to deny patent-eligibility where the claimed subject matter is obvious once the underlying natural law or natural phenomenon has been discovered, then this Court will have revived the framework set forth in 1948 by *Funk*. The manner in which the Circuit Courts of Appeal applied that framework in the 20 years following *Funk* suggests that this Court should be hesitant before endorsing that course. Rather, *Mayo*'s first aspect – a rejection of claims that amount to no more than a directive to apply a law of nature or a natural phenomenon – is the one most consistent with the historical precedents that *Mayo* itself invoked. The Court should apply that framework to the present case.

### B. The Requirement for an Inventive Application of a Law of Nature Revives the Analytical Framework of *Funk*.

*Funk* concerned claims to a mixture of bacteria that promoted nitrogen fixation in leguminous plants.

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[9] *See id.* at 1302. However, *Mayo* suggested that preemption *per se* is not the test for excluded subject matter. *See id.* at 1303.

[10] *See id.* at 1294, 1298.

Because each strain of bacteria was specific to a particular crop, a farmer planting multiple crops needed to apply multiple bacteria to his fields. However, different strains of bacteria tended to inhibit each other's activity, requiring the farmer to purchase and apply a separate inoculant to each crop. The patentee in *Funk* had discovered that particular strains of bacteria would not inhibit each other's activity when mixed together. He therefore disclosed, and claimed, a mixed inoculant of nitrogen-fixing bacteria selected for their mutual non-inhibitory qualities.[11]

This Court concluded that the patentee had not claimed an invention or discovery within the meaning of the patent statutes. The Court regarded the patentee's discovery of mutual non-inhibition as the discovery of a basic phenomenon of nature:

> Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable.[12]

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[11] Justice Frankfurter regarded the claims as unpatentable not because they were drawn to products of nature, but because the patentee had not provided sufficient disclosure to support claims encompassing all non-inhibitory mixtures of bacteria. *See* 333 U.S. at 133-34.

[12] *Id.* at 131.

The Court conceded that the patentee's discovery may have been "ingenious."[13] But patentability, in the Court's view, was predicated on the ingenuity in the application, not the ingenuity of the discovery. The patentee's application of the newly discovered principle was the production of a mixed culture. Once the patentee's discovery had been made, the application in the form of a mixed culture was well within the ordinary skill in the art:

> But once nature's secret of the non-inhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step. . . . That is to say, there is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed. All that remains, therefore, are advantages of the mixed inoculants themselves. They are not enough.[14]

Thus, under the *Funk* analysis, the patentee's discovery of a new law of nature or natural phenomenon was immaterial. What mattered was whether the patentee's application of that scientific discovery was inventive. To put it in the language of *Mayo*, given the natural phenomenon of non-inhibition,

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[13] *Id.*

[14] *Id.* at 132.

the patentee's application in the form of a mixed inoculant was nothing more than "well-understood, routine, conventional activity" already engaged in by workers in the field.[15]

If *Mayo* is to be understood as a requirement that a patentee's application of a law of nature or a natural phenomenon embody something more than the conventional or obvious, then it is difficult to distinguish *Mayo*'s analytical framework from *Funk*'s. To the contrary, in *Mayo* this Court grounded its requirement for an "inventive concept" beyond the law of nature in *Parker v. Flook*;[16] *Flook*, in turn, based its analysis on *Funk*.[17] Accordingly, if this Court interprets *Mayo* as denying patent-eligibility to a claim unless the claim embodies a non-obvious *application* of a scientific discovery, then this Court will have revived the analysis set forth in *Funk*.

The *Funk* analysis would appear to deny patent-eligibility of the claims challenged in this case.[18] The

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[15] 132 S. Ct. at 1298.

[16] *See id.* at 1294 (citing *Parker v. Flook*, 437 U.S. 584, 593 (1978), for requirement of "inventive concept").

[17] *Flook*, 437 U.S. at 591 ("*Mackay Radio* and *Funk Bros.* point to the proper analysis for this case: The process itself, not merely the mathematical algorithm, must be new and useful.").

[18] One might superficially distinguish *Mayo* from the present case on the grounds that *Mayo* concerned process claims, as compared to the compositions of matter at issue here. However, the claims in *Funk* were drawn to compositions of matter, and *Mayo* itself draws no distinction between categories of potentially patent-

claims in dispute are generally drawn to polynucleotides encoding *BRCA* polypeptides – a definition broad enough to encompass either isolated and purified genomic sequences, or isolated and purified cDNAs. Under the *Funk* analysis, the "natural phenomenon" discovered by the patentee appears to be the natural sequence of the *BRCA* loci. Once one eliminates the discovery in this case – the identification and sequencing of the *BRCA* loci – there is no apparent inventive application that would satisfy the *Funk* analysis. The application of that discovery – the purification and separation of the claimed DNA molecules from their natural contexts[19] – appears to have been obvious, given the routine nature of DNA manipulation at the time of invention.[20] But regardless of whether the claims in this case would pass muster under *Funk*, the historical experience of *Funk*'s analysis indicates that this Court should not endorse

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eligible subject matter. Moreover, this Court has made clear that the reasoning of *Funk* is equally applicable to product and process claims. *See Gottschalk v. Benson*, 409 U.S. 63, 67-68 (1972).

[19] There is no distinction between genomic DNA and cDNA under this analysis. While cDNA represent a species not found in nature, the processing and removal of intervening sequences in mRNA is performed by the cell itself. The human intervention – reverse transcription to cDNA – was entirely conventional at the time of the invention.

[20] One peculiar consequence of the "inventive application" analysis is that patent-eligibility appears to depend on the time the invention was made. What is routine and conventional now was revolutionary in the past. But the question of whether a claim is drawn to nothing more than a fundamental principle ought not to depend on the state of the art at the time.

an "inventive application" interpretation of *Mayo* in this case.

### C. Historical Application of the *Funk* Framework Illustrates the Risks of the Inventive Application Doctrine.

Prior to the creation of the Federal Circuit, the Circuit Courts of Appeal implemented *Funk*'s principle that a claim based on a newly discovered law of nature or natural phenomenon was not patentable, unless the patentee had added something more than conventional or obvious activity to the underlying principle. The range of seemingly meritorious claims that were invalidated for lack of an inventive application of a natural law should give this Court pause before it endorses that test in the present case.[21]

Two years after *Funk*, the Seventh Circuit applied *Funk*'s analysis in *Davison Chemical Corp. v. Joliet Chemicals, Inc.*[22] *Davison Chemical* dealt with a process for producing silica gel. While the process for making silica gel was known in the art, the patentee

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[21] The District Courts have begun applying the *Mayo* framework to question the validity of claims based on discovery of a new natural phenomenon. *See, e.g., Aria Diagnostics, Inc. v. Sequenom, Inc.*, No. C11-06391, 2012 WL 2599340, at *11-12 (N.D. Cal. July 5, 2012) (method of rapidly diagnosing fetal genetic abnormalities based on presence of cell-free fetal DNA in the maternal bloodstream); *Tessenderlo Kerley, Inc. v. Or-Cal, Inc.*, No. C11-04100, 2012 WL 2054994, at *5-6 (N.D. Cal. June 5, 2012) (method of treating crops with calcined kaolin based on discovery that particulates increase carbon dioxide absorption).

[22] 179 F.2d 793 (7th Cir. 1950).

had discovered that the temperature of the wash step determined the size of the gel's pores. He therefore claimed an improved process wherein the temperature of the wash step was adjusted to control the density of the final product.

But the Seventh Circuit regarded the relationship between wash temperature and pore size as a "newly discovered scientific fact."[23] Under *Funk*, it was necessary that the patentee's *application* of that fact be inventive. According to the court, once the relationship between temperature and pore size had been discovered by the patentee, the application in the form of the improved process was merely conventional and routine activity:

> [W]e assume that Connolly [the inventor] discovered that the temperature of the wash water determined the pore size and, therefore, the specific gravity or density of the gel but, we think, that, once having discovered this, it required nothing more than the ordinary skill of the scientist to determine that maintaining the temperature of the water at a constant point would make the size of the pore, and the density of the silica gel, uniform.[24]

The Seventh Circuit therefore held the patent invalid.

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[23] *Id.* at 794.

[24] *Id.* at 795.

The Court of Customs and Patent Appeals (CCPA) followed *Davison Chemical* in *In re Arnold*,[25] involving a claim to a process of electrostatic welding. The process of heating materials by alternating electrostatic fields was known. But the patent applicant discovered that molecules near the surface of a material responded more readily than interior molecules to alternating electrostatic fields.[26] By choosing a particular frequency based on the response of surface molecules, the applicant could selectively weld the surface of the material, or selectively weld a plasticizer applied to the surface.[27]

But according to the CCPA, the discovery that surface molecules had a different anomalous dispersion range compared to the interior molecules was a "phenomenon of nature" that had been discovered by the applicant.[28] The patentee's application – choosing a frequency that would selectively weld the surface molecules – was merely the result of his discovery. The claims accordingly lacked "invention" under *Funk*.[29]

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[25] 185 F.2d 686 (C.C.P.A. 1950).

[26] The basis for this effect was said to be the difference in anomalous dispersion range of a dipolar substance between the interior and surface molecules. *See id.* at 691.

[27] *See id.* at 688.

[28] *See id.* at 691.

[29] *See id*. Arnold did eventually succeed in patenting other claims from the same application. *See* U.S. Patent No. 2,575,251.

*National Lead Co. v. Western Lead Products Co.*[30] was similar to *Davison Chemical*. In a process for making a lead/lead oxide suspension (useful for storage batteries), the patentee had supposedly discovered that two different crystalline forms of lead oxide were present.[31] The patentee further claimed to have discovered that the temperature of the reaction determined the relative proportions of the two crystalline forms of lead oxide. By regulating the temperature of the reaction, the patentee could control the proportion of these two forms and thereby the uniformity of the final product. The patentee therefore claimed an improved process, in which the temperature of the reaction was held within particular ranges by regulating the rate of influx of molten lead.[32]

However, even assuming that the patentee had been the first to discover these phenomena, the Ninth Circuit held the process not patentable under *Funk*. The relationship between reaction temperature and product uniformity was considered to be a scientific fact or law of nature; the question was whether the patentee's application of that law was inventive.[33]

> Our inquiry must therefore focus upon whether an artisan, knowing that the temperature of the reaction determines the uniformity of the

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[30] 324 F.2d 539 (9th Cir. 1963).

[31] *See id.* at 541.

[32] *See id.* at 540.

[33] *See id.* at 542.

> product, would require more than ordinary skill to discover the process of controlling the reaction temperature by varying the feed of molten lead into the [prior art] Barton pot.[34]

Since the patentee used only conventional methods to regulate the temperature of the reaction, the method of performing the reaction at an optimized temperature was unpatentable.

Perhaps the most extreme example of this line of authority was the Third Circuit's decision in *Armour Pharmaceutical Co. v. Richardson-Merrell, Inc.*[35] The patentee made the surprising discovery that trypsin – a proteolytic enzyme with anti-inflammatory properties – could be absorbed by the small intestine and thereafter transported into the bloodstream.[36] The prior art had administered trypsin to patients via injection or other cumbersome methods. But in light of the small intestine's ability to absorb the enzyme, the patentee determined that oral administration would be possible if the trypsin was given a coating permitting it to resist digestion in the stomach and reach the small intestine intact.[37] The patentee therefore claimed a

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[34] *Id.*

[35] 396 F.2d 70 (3d Cir. 1968).

[36] *See id.* at 71-72. The discovery was unexpected, due to the large size of the trypsin molecule and the fact that the human body already secretes these enzymes into the digestion system.

[37] *See id.* at 72.

composition of trypsin given an enteric coating for use in the treatment of inflammation.[38]

Though the Third Circuit regarded the patentee's invention as precisely the sort of discovery the patent laws ought to protect,[39] the court felt bound by *Funk* to invalidate the claim. The ability of the small intestine to absorb trypsin and similar enzymes was a natural phenomenon. Under *Funk*, the test for patentability was whether anything more than ordinary skill would be necessary to reach the patentee's application of that discovery. The answer was no:

> Once nature's secret that the ileum would absorb trypsin was uncovered, any artisan would have known the process of enterically coating the trypsin to enable it to pass through the acidic environment of the stomach and continue into the ileum.[40]

And even if the patentee's discovery was the anti-inflammatory effect of trypsin administered to the

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[38] *See id.* at 71 n.3.

[39] *See id.* at 73: "Thus, it would seem that allowing a patent on the restricted use Martin made of his discovery of a natural phenomenon would not only be consistent with our patent laws, but would further their purpose. The employment of the newly discovered principle of nature would remain open to all those desiring to utilize it. We discern no requirement in the policy of the patent law that the method by which the discovery be utilized also be a new method. However, the Supreme Court and several courts of appeal have held to the contrary." (Footnote omitted.)

[40] *Id.* at 74.

small intestine, not merely the ability of the small intestine to absorb trypsin, the application of that newly discovered principle still lacked inventiveness under *Funk*.[41]

The claims in *Funk*, and in the *Davison Chemical* line as well, were invalidated for "lack of invention" – which, prior to the 1952 Patent Act, was a term encompassing the requirement defined as obviousness under 35 U.S.C. § 103.[42] Although *Funk* has been occasionally dismissed as a case about obviousness,[43] neither *Funk* nor the *Davison Chemical* line is an obviousness case. In neither of these cases would the claims have been obvious in the modern sense, because the patentee's discovery was not in the prior art. It was only upon the patentee's discovery of a "law of nature" that one of ordinary skill would have had reason to employ the conventional instrumentalities at issue in each case.

### D. The Modern Foundation of the Inventive Application Test Rests on a Misapprehension of Historical Precedent.

While *Funk* first articulated the requirement that a claim must embody a non-obvious application of a

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[41] *See id.* at 75.

[42] *Funk* and *Davison Chemical* were decided prior to the 1952 Patent Act, while *National Lead* and *Armour Pharmaceutical* were decided after.

[43] The Federal Circuit dismissed *Funk* on these grounds in the present case.

natural law, this Court's modern cases have grounded this principle on the Court of Exchequer's 1841 opinion in *Neilson v. Harford*,[44] which was also considered in *O'Reilly v. Morse*[45] and *Tilghman v. Proctor*.[46]

The patent in *Neilson* concerned the application of heated air to improve the performance of blast furnaces. On the question of whether Neilson had attempted to patent the abstract principle of applying heated air to the smelting process, or machinery embodying that principle, Baron Parke stated:

> We think the case must be considered as if the principle being well known, the plaintiff had first invented a mode of applying it by a mechanical apparatus to furnaces; and his invention then consists in this—by interposing a receptacle for heated air between the blowing apparatus and the furnace.[47]

*Flook* took this language to indicate that a fundamental principle underlying an invention should be regarded as part of the prior art, with a further "inventive concept" necessary to secure a patent.[48] Likewise, *Mayo* suggested that the patent in *Neilson*

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[44] Webster's Patent Cases 295 (1841).

[45] 56 U.S. 62 (1853).

[46] 102 U.S. 707 (1880).

[47] Webster's Patent Cases at 371.

[48] *Flook*, 437 U.S. at 592, 594.

was sustained because the patentee had applied unconventional steps to confine the claims to a particular useful application.[49] Unfortunately, *Flook* and *Mayo* relied on a mistaken interpretation of *Neilson*.

In *Neilson*, the Court of Exchequer did not condition patentability on an inventive application of a natural law. What guided the Court of Exchequer was the distinction between patenting an abstract principle divorced from any mode of applying it for practical use, and patenting a new mode of applying a principle toa particular practical use. The same distinction should guide this Court in this case.

The issue of patentability in *Neilson* was sufficiency of disclosure: whether the patentee had sufficiently disclosed his method of heating air prior to introduction into the furnace.[50] The defendants charged that the patentee had failed to describe the invention such that one of ordinary skill in the art could carry out the

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[49] *Mayo*, 132 S. Ct. at 1300.

[50] Though the defendant's plea in *Neilson* included the defense that the patent was void "as being for a principle," Webster's Patent Cases at 296, the defendant's argument was focused almost entirely on insufficiency of disclosure. The defendant's motion for a new trial was grounded on this issue, as well as alleged errors in the specification and discordance between the patent's specification and title. *See id.* at 330. According to the defendants, the inventor did not even understand the principle behind his invention. *See id.* at 344 ("It has been said that Mr. Neilson was not aware of the nature and principle of his discovery.").

invention[51] – an argument that today would be phrased as lack of enablement under 35 U.S.C. § 112. For example, the patent did not disclose the shape and size of the heating vessel, nor how one of ordinary skill in the art could scale up the process from the small forges that Neilson had employed.[52]

Ultimately, the patent was sustained not because Neilson's apparatus was inventive, but because it was *largely conventional*. Both the patentee and the court emphasized that the heating of air and the apparatus Neilson employed were well known in the art.[53] Neilson discovered the effect of heating air before its introduction into the furnace and disclosed a mode for heating air in its passage from the blowing apparatus to the furnace. Because the heating of air in various kinds of vessels was routine and conventional in the art, one of ordinary skill in the art could readily devise other machinery achieving the same end.[54] The patent was therefore not invalid for lack of sufficient disclosure.

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[51] *See, e.g., id.* at 307-09 (defendant's argument that disclosure did not enable practice of the invention).

[52] *See id.* at 339.

[53] *See id.* at 337 (interposition of Baron Alderson); *id.* at 344 (patentee's argument: "The mode of heating air was perfectly well known; it was no discovery of Mr. Neilson's, every body knew it.").

[54] *See id.* at 372 (patentee proved to jury that "competent workman" could vary the shape of the air vessel to achieve desired effect).

Contemporary opinions not only underscore this understanding of *Neilson*, but in fact refute the interpretation suggested in *Mayo* and *Flook*. As discussed by this Court in *Risdon Iron & Locomotive Works v. Medart*[55] and *Tilghman*,[56] the Court of Session considered the same patent in Scottish infringement proceedings shortly after *Neilson*.[57] Lord Justice Hope instructed the jury on the distinction between an unpatentable "abstract philosophical principle"[58] (such as a law of nature or property of matter) and a patentable application of that principle to practical ends. But that distinction was *not* based on whether the patentee's application of that fundamental principle was in itself inventive:

> The main merit, the most important part of the invention, may consist in the conception of the original idea—in the *discovery of the principle in science, or of the law of nature*, stated in the patent, and *little or no pains may have been taken in working out the best manner and mode of the application of the principle* to the purpose set forth in the patent.[59]

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[55] 158 U.S. 68, 73 (1895).

[56] 102 U.S. at 725.

[57] *Household Coal & Iron Co. v. Neilson*, Webster's Patent Cases 673 (1843).

[58] *Id.* at 683.

[59] *Id.* (emphasis added). "It would be very strange and unjust," added Justice Hope, to deny patentability to the application of a

In other words, patentability did not depend on whether the patentee's practical application added something beyond the conventional and obvious to an underlying law of nature or a natural phenomenon.[60]

This understanding of *Neilson* – that one may not patent a fundamental principle in the abstract, divorced from its mode of application – was the understanding relied on by this Court in *Morse*. Morse was not denied his eighth claim because his application of the newly discovered "galvanic current" was merely conventional or routine.[61] It was because he invented only a particular mechanism, not a universal means for electromagnetic communication.[62] *Morse*, like *Neilson*, was a case about patent scope: given the state of the art, was the patentee's disclosure sufficient to enable application of the principle embodied in his mode of

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principle on the grounds that the inventor had discovered the principle as well as its practical application. *Id.* at 684.

[60] Justice Hope's instructions were affirmed by the House of Lords on appeal, but an error on the question of abandonment required a new trial. *See id.* at 708-17 (overruling defendant's exceptions based on specification, but granting new trial on the question of prior public use).

[61] Quite the opposite: the Court noted that Morse's application depended on "certain complicated and delicate machinery, adjusted and arranged upon philosophical principles, and prepared by the highest mechanical skill." *Morse*, 56 U.S. at 117.

[62] *Id.* ("But Professor Morse has not discovered, that the electric or galvanic current will always print at a distance, no matter what may be the form of the machinery or mechanical contrivances through which it passes.").

application? In both *Neilson* and *Tilghman* the answer was yes: the patentee had invented a mode of application of a natural principle, and his patent extended to other applications in that same mode. In *Morse* the answer was clearly no: Morse was entitled to claim his mode of application of the electromagnetic force, but not the universal use of the electromagnetic principle for communication at a distance.

That long-standing distinction[63] – between a claim directed to a fundamental principle in the abstract and a claim directed to a particular mode of application of a fundamental principle – is what should guide the Court in this case.[64] This Court should make clear that *Mayo* denied patent-eligibility to the claimed process not because it was obvious in light of the underlying discovery, but because it amounted to nothing more than a directive to apply a natural law. It therefore attempted to monopolize a law of nature in the abstract, unbounded by a mode of applying that law to a particular practical use.

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[63] *See also* 1 William C. Robinson, *The Law of Patents* § 137, 141 (1890) (distinguishing between "principle" as unpatentable natural physical force and "principle" as inventor's idea of operative means applied to practical effect).

[64] This distinction is consistent with *Flook*, which dealt not with a newly discovered law of nature or natural phenomenon, but with an abstract idea. This Court also emphasized the unpatentability of abstractions in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

## IV. CONCLUSION

In this case the Court should reject an interpretation of *Mayo* that would revive the "inventive application" analysis of *Funk*. Instead, the Court should endorse an interpretation of *Mayo* that denies patent-eligibility to claims that do nothing more than direct the application of a natural law without reference to a specific mode of application.

The claims at issue in this case are drawn to particular isolated and purified DNA molecules: synthetic derivatives of natural genes. Unlike the claims in *Mayo*, they do not represent abstract fundamental principles, unbounded by the patentee's mode of application. This Court should therefore affirm the judgment of the Federal Circuit, and hold that claims to isolated and purified DNA molecules derived from human genes are not invalid for lack of patent-eligibility under 35 U.S.C. § 101.

Respectfully submitted,

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