No. 11-725

IN THE

Supreme Court of the United States

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, ET AL.,

Petitioners,

v.

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

Respondents.

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

AMICI BRIEF OF CERTAIN ACADEMICS IN LAW, MEDICINE, HEALTH POLICY AND CLINICAL GENETICS IN SUPPORT OF PETITIONERS

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INTEREST OF THE AMICI CURIAE[1]

Amici Curiae are academics in law, medicine, health policy and clinical genetics. Collectively, they have advised the governments of the United States, Canada and Australia, as well as international governmental organizations including the Organisation for Economic Co-operation and Development (OECD) and the World Health Organization on human gene patents and life science innovation. Specifically, they chaired a task force of the Secretary's Advisory Committee on Genetics, Health and Society on human gene patents, testified before Congress on genetic testing, drafted guidelines for the OECD on the licensing of genetic inventions, prepared a report for the OECD on IP management in the life sciences, drafted reports for the U.S. Congress, prepared multiple case studies on gene patenting in the United States and prepared submissions to Australian law reform inquiries into gene patenting.

Dr. E. Richard Gold, LLB, S.J.D., is a James McGill Professor in the Faculty of Law at McGill University. He has authored an extensive case study of Myriad Genetics and its patenting policies and was the Expert Consultant

1. The parties were given at least ten days notice of amici's intention to file a brief. The petitioners have filed a letter of blanket consent to filing amicus briefs and letter is lodged with the Clerk. The respondents granted consent to the amici on December 29, 2011 via electronic mail. Pursuant to this Court's Rule 37.6, the amici submitting this brief and their counsel hereby represent that no party to this case nor their counsel authored this brief in whole or in part, and that no person other than amici, using research funds provided by VALGEN, paid for or made a monetary contribution toward the preparation and submission of this brief.

who drafted the OECD Guidelines on the Licensing of Genetic Inventions. He practiced law in the areas intellectual property licensing and financing of small to medium technology companies and has provided judicial education in the United States, Canada and France on questions of intellectual property, property and the life sciences. He also heads intellectual property and technology transfer research within the Value Addition through Genomics and GE^{3}LS (VALGEN), a publicly financed research project on agriculture and crop biotechnology.

Dr. James P. Evans, M.D., Ph.D., is Bryson Distinguished Professor of Genetics and Medicine in the School of Medicine at the University of North Carolina. He is a board certified Medical Geneticist and Internist with extensive clinical and research expertise in the area of genetics and genetic testing, including the analysis of the BRCA1/2 genes in both the research and clinical setting. He chaired the Task Force that laid the groundwork for *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Testing: Report of the Secretary's Advisory Committee on Genetics, Health, and Society* (U.S. Department of Health and Human Services, April 2010). He is also the editor-in-chief of *Genetics in Medicine*, the journal of the American College of Medical Genetics.

Dr. Tania Bubela, Ph.D., J.D., is Associate Professor of health and intellectual property law in the School of Public Health at the University of Alberta. She has written and consulted extensively on the commercialization of genomics research and the process of technology transfer. She has active research grants in the fields of mouse

models for human disease, synthetic biology and DNA barcoding. She leads a publicly funded research project on legal, economic and institutional barriers to translational stem cell research.

Dr. Robert Cook-Deegan, M.D., is Director of Genome Ethics, Law and Policy at the Institute for Genome Sciences and Policy at Duke University. He is also a Research Professor of Public Policy, of Medicine, and of Biology. He helped co-found the DNA Patent Database at Georgetown University, and was the principal investigator for a series of case studies on the impact of patenting and licensing on clinical access to genetic testing prepared for the U.S. Secretary's Advisory Committee for Genetics, Health and Society (noted above).

Dr. Dianne Nicol, Ph.D., L.L.M., is a Professor of Law in the Faculty of Law at the University of Tasmania, Australia and Deputy Director of the Centre for Law and Genetics, based at the University of Tasmania. She has conducted research and written extensively on intellectual property in biotechnology and commercialization of biomedical research.

SUMMARY OF ARGUMENT

Certiorari is required to correct legal errors introduced by the Federal Circuit that will cause uncertainty not only in the field of human clinical genetics but across the life sciences generally. The majority's decision conflicts with decisions of this Court, most notably *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) and *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). This case also provides the Court with the opportunity to develop its holding in

Bilski, which called for a subtle understanding of the relationship between 35 U.S.C. § 101 and §§ 102, 103, and 112.

The Federal Circuit introduced confusion into the determination of patent eligibility under § 101 in at least four respects: (1) it introduced a bright-line test of covalent bond-breaking for patent eligibility of naturally occurring biological molecules; (2) it set out two conflicting tests of the meaning of "markedly different" under this Court's holding in *Chakrabarty*; (3) it assessed the claims from the point of view of a chemist when the patent applicant had specifically set out the field of art as being genetics; and (4) it overrode the majority of judges on the panel because of expectations settled by administrative, not legal, rules.

Because the effects of this decision will be felt in many areas of the life sciences in which natural molecules are involved, it is critical that this Court provide guidance in line with its decision in *Bilski* on the application of § 101 to natural molecules and the important role that § 101 plays in facilitating substantive analysis under §§ 102, 103, and 112.

ARGUMENT

Certiorari is required in this case to correct the introduction by the Federal Circuit of a bright-line, yet scientifically incoherent test, for patentability under 35 U.S.C. § 101. This Court's holding in *Bilski* calls for a more subtle analysis of § 101 than was given by the majority in the Federal Circuit. This appeal presents the Court with an opportunity to explore the relationship it described in *Bilski* between the threshold test for patentable subject-matter under § 101 and the more substantive analyses to

be undertaken under §§ 102, 103, and 112.

I. THE DECISION OF THE FEDERAL CIRCUIT INTRODUCES CONFUSION INTO AN IMPORTANT AREA OF FEDERAL LAW

The Federal Circuit introduced significant uncertainty into determinations of the patent-eligibility of biological molecules under 35 U.S.C. § 101 of the Patent Act. As naturally occurring biological molecules are ubiquitous not only in clinical genetics but in the life sciences generally—including medicine, agriculture, aquaculture, tree biotechnology, industrial biotechnology and new forms of energy—the majority's decision sows confusion in a critical area of federal law with effects across many industries throughout the United States.

In particular, the majority in the Federal Circuit creates the following four forms of uncertainty:

1. It asserts an arbitrary and scientifically illegitimate defining boundary between the claimed invention and nature: the cleavage of a covalent bond (App. at 48a ("But a covalent bond is the defining boundary between one molecule and another").) There is nothing unique regarding the importance of covalent bonds in chemistry or biology. Indeed, other types of bonds—such as the hydrogen bonds linking base pairs on opposing DNA strands that are critical for both replication and transcription and the ionic bonds that link histones to the DNA backbone that are essential to transcription—are at least as important. Hydrogen bonds between purines and pyrimidines, in particular, are features

of DNA structure that are taught in textbooks as essential to its biological function.

2. It sets out conflicting criteria to determine whether a claimed invention constitutes eligible subject-matter under § 101. The majority opinion of Judge Lourie took the position that a structural difference between the claimed matter and natural product was sufficient to meet the requirements of § 101 whereas both the concurring opinion of Judge Moore and the dissent of Judge Bryson stated that the claimed matter must be both structurally and *functionally* different from a natural product to so qualify.

3. It assesses patent eligibility of claims from the point of view of a person having ordinary skill in the art (PHOSITA) of *chemistry* rather than of *genetics*, despite the clear application of the claimed invention in the life sciences and the specific statement of the patent applicant;

4. Because of its reliance on the concurring opinion of Judge Moore, the majority in the Federal Circuit overrides a majority of the judges in the Federal Circuit who found that isolated DNA sequences of most or all of a gene were *prima facie* not patentable subject-matter under § 101.

A. Cleavage of a Covalent Bond as Test for Patent-Eligibility Introduces Uncertainty

The majority of the Federal Circuit held that the claimed isolated DNA molecules were chemically distinctive from DNA in the human body (App. at 46a)

because Myriad had cleaved "a covalent bond [which] is the defining boundary between one molecule and another." (App. at 48a.) This argument introduces a test of patent eligibility under § 101—the breaking of covalent bonds—that is inappropriate and sows confusion in determining which naturally occurring biological molecules, in fields well beyond clinical human genetics, are eligible to be patented.

The Federal Circuit failed to provide a reason that covalent, rather than other types of bond—in particular ionic and hydrogen bonds—are the features that distinguish what is patentable from that which is not patentable. The majority's only explanation is based on a fundamental misunderstanding of a seminal 1960s text on chemistry: "But a covalent bond is the defining boundary between one molecule and another. The dissent's citation of Linus Pauling's comment that covalent bonds 'make it convenient for the chemist to consider [the aggregate] as an independent molecular species' underlines the point." (App. at 48a.)

The majority's misreading of Pauling actually proves the point opposite to that it was making. Pauling was talking of chemical bonds in general—which also include ionic and hydrogen bonds—rather than only covalent bonds. The actual quote from Pauling is "that there is a *chemical* bond between two atoms or groups of atoms in case that the forces acting between them are such as to lead to the formation of an aggregate with sufficient stability to make it convenient for the chemist to consider it as an independent molecular species." Linus Pauling, The Nature of the Chemical Bond and the Structure

OF MOLECULES AND CRYSTALS: AN INTRODUCTION TO MODERN STRUCTURAL CHEMISTRY 6 (3d ed. 1960) (emphasis added). Pauling defined *chemical* bond on the previous page as including "electrostatic bonds [which include both ionic and hydrogen bonds], covalent bonds and metallic bonds." *Id.* at 5.

Indeed, hydrogen bonds, and not covalent bonds, are the defining characteristic of DNA. While covalent bonds certainly play an important role in biology, and provide DNA chemical stability as the repository of genetic information, other bonds are of specific significance in the field of genetics. The essence of DNA, its information-carrying capacity and its ability to replicate, is directly dependent upon hydrogen bonds that link the base pairs in opposing strands. It is an antisymmetrical double helix precisely and only because of hydrogen bonds, not the covalent bonds in the backbone. Similarly, the ability of DNA to copy itself (replication) and the transcription of DNA into RNA rely both on hydrogen bonds and the ionic bonds connecting histones and DNA-binding proteins that turn on and off transcription.

Even the concurring opinion expressed doubt as to whether the cleavage of covalent bonds was sufficient to establish the patent eligibility of isolated DNA sequences: "If I were deciding this case on a blank canvas, I might conclude that an isolated DNA sequence that includes most or all of a gene is not patentable subject matter." (App. at 79a.)

The problem with the majority's decision is far deeper, however, than the arbitrariness with which it highlighted the role of covalent bonds over other types of bond: the

majority failed to provide a substantive rationale of why the cleavage of *any* bond should be the key to determining patent-eligibility under § 101. It cited no cases to support this decision and failed to consider the effect of its novel test on the patentability of other naturally occurring biological molecules, such as proteins, and other naturally occurring structures, such as cell lines. Claims reading over isolated proteins would seemingly fail the majority's test as no covalent bond would normally be cleaved. This would have a profound effect not only in the limited area of human clinical genetics, but across all of biology from regenerative medicine (*e.g.*, U.S. Patent No. 8,057,788 (filed Dec. 28, 2006), directed to placental stem cells, assigned to the Anthrogenesis Corporation of New Jersey); to agriculture (e.g., U.S. Patent No. 8,067,669 (filed Mar. 5, 2010), directed to a protein to inhibit soya rust, assigned to The University of Missouri); industrial applications (*e.g.*, U.S. Patent No. 8,034,600 (filed Aug. 5, 2008), directed to a protein used in starch and alcohol production, cleansing and textiles, assigned to Danisco U.S. of California); and energy (*e.g.*, U.S. Patent No. 8,004,264 (filed Sept. 23, 2008), directed to proteins that enhance the use of wood, agricultural crops and other organic materials into ethanol, assigned to Novozymes, Inc. of California).

None of this Court's decisions would call for the bright-line test developed by the majority in the Federal Circuit. This Court has repeatedly warned against the use of arbitrary tests in the application of § 101 (*see e.g.*, *Bilski*). The majority's decision violates this rule, introducing a test for patent-eligibility that is not only unsupported by legislation, case law or scientific principle, but that creates significant uncertainty over the patent-eligibility of a large range of naturally occurring biological molecules.

B. Conflicting Tests for Patentable Subject-Matter under § 101

While the majority opinion found isolated DNA sequences to constitute patentable subject-matter under § 101, the two members of the majority disagreed on the legal rule to be used in arriving at this decision, sowing further confusion for the application of this rule in the future.

Judge Lourie, in the majority decision, interpreted this Court's decision in *Chakrabarty* as drawing "a line between compositions that, even if combined or altered in a manner not found in nature, and compositions that human intervention has given 'markedly different,' or 'distinctive,' characteristics." (App. at 45a.) He then gave an interpretation of "markedly different" and "distinctive" that reduced the meaning of these terms to require a structural difference, even if not directly relevant to what renders the invention inventive: "We disagree, as it is the distinctive nature of DNA molecules as isolated compositions of matter that determines their patent eligibility rather than their physiological use or benefit." (App. at 49a.)

Both the concurring opinion and the dissent interpreted *Chakrabarty* more in line with its literal meaning, as requiring more than a mere structural difference between the claimed invention and naturally occurring DNA sequences. The concurring opinion noted that "[a]lthough the different chemical structure does suggest that claimed DNA is not a product of nature, I do not think this difference alone necessarily makes isolated DNA so 'markedly different,' from chromosomal DNA so as to be per se patentable subject matter." (App. at 75a.) (citation omitted.)

Similarly, the dissent found that a claimed invention must exhibit both structural and functional differences from natural compositions of matter. "In sum, the test employed by the Supreme Court in *Chakrabarty* requires us to focus on two things: (1) the similarity in structure between what is claimed and what is found in nature and (2) the similarity in utility between what is claimed and what is found in nature." (App. at 105a.)

The result of these different opinions is that, while the majority of the Federal Circuit held that structural differences between a naturally occurring biological compound and a claimed invention were sufficient to meet the requirements of § 101, a majority of judges found that a functional difference was also required. This outcome establishes an impossible set of rules for future courts attempting to apply § 101.

C. The Federal Circuit Relies on the Wrong PHOSITA

In *Ultramercial, LLC v. Hulu, LLC*, 657 F.3d 1323 (Fed. Cir. 2011), the Federal Circuit recognized the importance of providing context for a claim prior to an analysis of its patent-eligibility under § 101. "On many occasions, however, a definition of the invention via claim construction can clarify the basic character of the subject matter of the invention. Thus, claim meaning may clarify the actual subject matter at stake in the invention and can enlighten, or even answer, questions about subject matter abstractness." *Id.* at 1325.

While the court in *Ultramercial* did not explicitly address whether claim construction for purposes of

patent-eligibility under § 101 follows the general rules of claim construction for patent infringement, its clear implication was that it did. Nevertheless, the majority in the Federal Circuit in the case under appeal chose not the PHOSITA in the field specifically noted by the patent applicant, nor a scientist in the life sciences (a geneticist or biochemist), but a chemist who would not be specifically knowledgeable about the invention, its utility or its import. In so doing, the majority created confusion in the construction of life science claims.

In the case under appeal, the Federal Circuit began the process of claim construction by situating the claims in light of the understanding that a chemist would bring to the claimed invention. "We recognize that biologists may think of molecules in terms of their uses, but genes are in fact materials having a chemical nature and, as such, are best described in patents by their structures rather than their functions." (App. at 49a.) Based on the understanding of a chemist, the majority held that: "Although isolated DNA must be removed from its native cellular and chromosomal environment, it has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body." (App. at 47a.)

While the majority was correct in placing the claim within the context of a specific art to which it applies, it selected the wrong PHOSITA. As noted by the dissent: "[I]f we are to apply the conventional nomenclature of any field to determine whether Myriad's isolated DNA claims are 'new,' it would seem to make more sense to look to genetics, which provides the language of the claims, than to chemistry." (App. at 101a.)

Further, the patent documents prepared by Myriad point directly to the field of genetics rather than to chemistry. In fact, the opening line in several sections, including the abstract and description, of U.S. Patent No. 5,747,282 (filed June 7, 1995) states: "The present invention relates generally to the field of human genetics."

The majority's error in selecting a PHOSITA permeates its decision. In particular, it leads the majority to the biologically incorrect conclusion that:

> It is undisputed that Myriad's claimed isolated DNAs exist in a distinctive chemical form—as distinctive chemical molecules—from DNAs in the human body, *i.e.*, native DNA. Native DNA exists in the body as one of forty-six large, contiguous DNA molecules. Each DNA molecule is itself an integral part of a larger structural complex, a chromosome. In each chromosome, the DNA molecule is packaged around histone proteins into a structure called chromatin, which in turn is packaged into the chromosomal structure.
>
> Isolated DNA, in contrast, is a free-standing portion of a native DNA molecule, frequently a single gene. Isolated DNA has been cleaved (*i.e.*, had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule. For example, the *BRCA1* gene in its native state resides on chromosome 17, a DNA molecule of around eighty million nucleotides. Similarly, *BRCA2* in its native state is located

> on chromosome 13, a DNA of approximately 114 million nucleotides.

(App. at 45-46a) (citations and cross-references omitted.)

The above conclusion ignores biological reality by assuming that native DNA exists solely in the form of large, contiguous chromosomes and that smaller strands of DNA are not natural. In fact, DNA naturally exists (for example during replication) within organisms in varying lengths that are much smaller than an entire chromosome, as assumed by the majority. It is entirely expected, for example, for a DNA molecule, smaller than an entire chromosome but comprising the entirety of the claimed DNA sequence, to exist in nature. Such a molecule would regularly be created within cells during replication, through normal mistakes in DNA transcription or through the cleavage of a covalent bond within the chromosome caused by a natural chemical agent. In fact, ironically, BRCA1 and BRCA2 proteins apparently play a role in repairing just such cleavages. *See* Ashok R. Venkitaramen, *Cancer Susceptibility and the Functions of BRCA1 and BRCA*, 108(2) CELL 171 (2002).

Given the differences between a chemist and a geneticist in appreciating the biochemistry of the cell, the majority decision introduces significant confusion in determinations of patent-eligibility under § 101.

D. The Federal Circuit Overrode a Majority of its Judges who Found Prima Facie Lack of Patent Eligibility

This Court made clear that determinations of patent-eligibility are to be based on the ordinary meaning of

§ 101 and the three exceptions recognized by courts for over a century: laws of nature, physical phenomena, and abstract ideas all of which, this Court held, "are consistent with the notion that a patentable process must be 'new and useful.'" *Bilski*, 130 S. Ct. at 3225. The Court held that "the Judiciary [does not have] *carte blanche* to impose other limitations that are inconsistent with the text and the statute's purpose." *Id.* at 3226.

Nevertheless, the majority of the Federal Circuit overrode the prima facie determination of a majority of the panel's judges who found that "an isolated DNA sequence that includes most or all of a gene is not patentable subject matter." (App. at 79a.) The concurring opinion, upon which the majority depended, did so out of a fear that this conclusion would disturb the expectations of the biotechnology industry. (App. at 82a.)

The concurring opinion and the dissent agreed that isolated DNA sequences of most or all of a gene were not 'markedly different' from natural DNA sequences, as required by Chakrabarty. The concurring opinion, after stating that an invention must have more than structural differences from its natural counterpart to be patent-eligible under §101 (App. at 75a), held that isolated DNA sequences of most or all of a gene did not meet this test: "Despite the literal chemical difference, the isolated full length gene does not clearly have a new utility and appears to simply serve the same ends devised by nature, namely to act as a gene encoding a protein sequence" (App. at 79a). The dissent found that neither isolated short DNA sequences nor isolated sequences of most or all of a gene constituted patentable subject matter: "I respectfully dissent, however, from the court's holding that Myriad's

BRCA gene claims and its claims to gene fragments are patent-eligible". (App. at 94a.)

The concurring opinion overrode its holding on the application of the "markedly different" test in Chakrabarty to claims reading over isolated DNA sequences of most or all of a gene out of fear of upsetting settled expectation of the biotechnology industry. In doing so, it cited this Court in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 739 (2002), stating "that courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community. In that case, we made it clear that the doctrine of equivalents and the rule of prosecution history estoppel are settled law." (citations omitted).

Unlike the situation in *Festo*, there is no settled law that holds isolated DNA sequences to be eligible subject-matter under the 35 U.S.C. § 101. At best, expectations have been built around the U.S. Patent and Trademark Office's interpretation that those sequences constitute eligible subject-matter. However, no deference is given to the Patent Office's interpretation as determinations of patent eligibility are pure questions of law. *Arrhythmia Research Tech. v. Corazonix Corp.,* 958 F.2d 1053, 1055 (Fed. Cir. 1992). Patent applicants know this rule well and would not confuse Patent Office interpretation with settled law.

The concurring opinion's views of the effect of a decision holding that claims reading over DNA sequences of most or all of a gene are highly disputed. A recent task force established by the Secretary of Health concluded that patents have had little or no effect on bringing new

clinical diagnostics, such as those claimed by Myriad, to market. Secretary's Advisory Comm. on Genetics, Health, and Society, Dep't of Health and Human Services, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (2010). In fact, in all cases studied, non-patent holders were first to market and the entry of the patent holder reduced the number of test providers rather than enhancing access or availability of a new test, Robert Cook-Deegan, et al., *The Dangers of Diagnostic Monopolies,* 458 Nature 405 (2009).

The history of the sequencing of the BRCA1 and BRCA2 genes, their subsequent patenting, and the introduction of genetic testing is illustrative of the complex environment in which patents operate in the field of human genetics. The race to sequence these genes was highly competitive, with different teams publishing *BRCA2* results only a day apart. Myriad was not the first to make diagnostic genetic testing for these genes available on the market but, when it did enter the market, it shut out what it viewed as competitors, including university laboratories. E. Richard Gold and Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm,* 12(4) Genetics in Medicine S39 (2010). Contributions to the breast cancer mutation database, the Breast Cancer Information Core hosted by the National Human Genome Research Institute, were reduced both because of fear of being sued by Myriad and, after 2004, by Myriad's unilateral decision not to contribute mutations it found to the database. Julia Carbone, et al., *DNA patents and diagnostics: not a pretty picture*, 28 Nature Biotechnology 784 (2010). There is no evidence that patents did anything to enhance the development or improvement of clinical tests for *BRCA1*

and *BRAC2*, Gold and Carbone, *supra.*, and some evidence that it decreased patient access, Cook-Deegan, *supra.*

While settled expectations are relevant in certain situations, here those expectations were built around administrative practice, not legal rules, and may undermine, rather than enhance, innovation.

II. THE DECISION OF THE FEDERAL CIRCUIT CONFLICTS WITH DECISIONS OF THIS COURT WITH RESPECT TO THE SCOPE OF § 101

The decision of the majority in the Federal Circuit deviated in important respects from this Court's decisions in *Chakrabarty* and in *Bilski* both by imposing artificial limitations on these decisions and by ignoring this Court's admonishment not to introduce limitations in the Patent Act that do not appear from an ordinary reading of that statute.

As noted in section I.B., the majority opinion restricted this Court's teaching in *Chakrabarty* that inventions must be "markedly different" from natural substances. Instead, the majority required structural difference, regardless of its relevance to the invention. The majority opinion implicitly recognized the difficulty of its position when it held that snapping a leaf off of a tree would not be eligible subject-matter despite the fact that many bonds would necessary be cleaved in the process. (App. at 52a.) Nevertheless, the majority provided no explanation for why snapping the leaf would not be patent-eligible under its test. It is unlikely that such an explanation exists that would be consistent with this Court's rulings.

Further, as argued in section I.A., the majority decision ignores this Court's warning in *Bilski* not to impose limitations on the ordinary meaning of the Patent Act as the majority restricted the test of patentable subject-matter in naturally-occurring organic chemicals to the cleavage of covalent bonds. Artificially reducing the assessment of patentable-subject matter to a single factor ignores the broad framework established by the Patent Act. While perhaps rendering the statute easier to manage by the courts, the imposition of arbitrary rules does not advance the general objective of the statute to promote science and technology and sows confusion when applied in contexts outside the case in question.

At a more general level, this appeal provides the Court with an opportunity to assess, for the first time, claims covering naturally occurring molecules that have not been altered in such a manner as to change their function or utility. This Court's holding in *Bilski*, which sets out the framework for this analysis, was recently followed in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011). In *Classen*, the Federal Circuit elaborated that the threshold test under § 101 was met if the claimed invention was both "within the general classes of § 101 subject matter and not manifestly abstract." *Id.* at 1066. The majority in the Federal Circuit in the case under appeal undertook the first part of this test—albeit, for reasons presented in section I.A. on the basis of a scientific error—but not the second.

CONCLUSION

Because of the uncertainty that the Federal Court injected into a critical area of federal law that extends across all of the life sciences as well as the conflict between the decision of the Federal Circuit and those of this Court, the petition for certiorari should be granted.

Respectfully submitted,

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