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 OF *AMICUS CURIAE* DR. ANANDA MOHAN CHAKRABARTY IN SUPPORT OF RESPONDENTS

CRAIG E. COUNTRYMAN
Fish & Richardson P.C.
12390 El Camino Real
San Diego, CA 92130
(858) 678-5070
countryman@fr.com

JONATHAN E. SINGER
Counsel of Record
Fish & Richardson P.C.
3200 RBC Plaza
60 South Sixth Street
Minneapolis, MN 55402
(612) 335-5070
singer@fr.com

Counsel for Amicus Curiae

2013 – Bachman Legal Printing ■ (612) 339-9518 ■ 1-800-715-3582 ■ Fax (612) 337-8053

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

REGULATIONS

OTHER AUTHORITIES

INTEREST OF *AMICUS CURIAE*[*]

Dr. Ananda Mohan Chakrabarty is the inventor of the human-made bacteria, useful for treating oil spills, that this Court found was patent-eligible in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Following that case, Dr. Chakrabarty has remained interested in patent law and has written several articles discussing 35 U.S.C. § 101 and its application to patenting human genes. *See, e.g.,* Arsenio M. Fialho & Ananda M. Chakrabarty, *Patent controversies and court cases: cancer diagnosis, therapy and prevention*, 13 CANCER BIOL. THER. 1229 (2012).

Dr. Chakrabarty is a Distinguished University Professor at the University of Illinois at Chicago in its Department of Microbiology and Immunology. He is an inventor on 25 U.S. patents and has founded two companies applying his research to developing anti-cancer therapies. He has also advised the United States, the United Nations, NATO, and other foreign governments on scientific and legal matters.

Dr. Chakrabarty's current research is focused on using bacterial proteins to treat and prevent cancer. His research has shown that a protein called azurin has great promise for treating breast cancer and other diseases. The disclosures in the Myriad patents, and others like them, can be used to identify people who may benefit from clinical testing of azurin.

---

[*] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus* or his counsel made a monetary contribution to its preparation or submission. Petitioners filed a letter with the court consenting to the filing of any *amicus* brief. Respondents have consented to the filing of this brief.

INTRODUCTION

Cancer is a scourge that we must fight. Nearly all cancers are due to mutations in the human genome. Isolated human genes reflecting those mutations are among the best tools for diagnosing the risk a patient will develop cancer, and for designing drugs to treat the cancer or prevent its emergence. The mutations are challenging and expensive to identify and to characterize. But, once isolated, they possess a specific, credible, and substantial utility absent in nature. Myriad's patents to the isolated *BRCA1* and *BRCA2* mutations, for example, enable doctors to identify women at a high risk of breast or ovarian cancer, allowing early detection and intervention. The isolated mutations enable researchers to develop drugs targeted to fighting the cancer. And the isolated mutations enable scientists, including myself, to identify women who might benefit from new therapies that can arrest or prevent cancer.

"Are human genes patentable?" I submit the answer should be yes for isolated portions of genes that possess a specific, substantial, and credible utility different from what is found in nature. The uses of the isolated *BRCA1* and *BRCA2* mutations meet this requirement. Relying on utility as the dividing point is consistent with this Court's precedent, the text of § 101, and the PTO Guidelines. It also ensures that patents encourage the development of useful technology but do not tie up "wild-type" genes or isolated genes that have not been applied to a useful end.

The Court should not require an isolated gene (*i.e.*, a gene detached and separated from the adjoining genes in the chromosome) to have any particular degree of structural difference from what exists in nature to be patentable, aside from the differences

identified by the Federal Circuit. Seemingly small structural changes to biological substances often cause major changes to function. Focusing on a substance's function, rather than its structure, will ensure that patents promote the disclosure and production of useful inventions.

Any concerns that patents on isolated human genes with a specific utility will impede research and medical treatment can be addressed by appropriately tailoring the remedies for patent infringement. Current law provides at least two ways to do this.

First, after *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), district courts often cite the public interest to deny injunctions in patent cases and allow the defendant to continue its activities in exchange for a royalty set by the court. So injunctions will almost always be unavailable against researchers who seek to advance scientific knowledge. And they may even be unavailable against competitors if the facts show it would be better for patients, such as by improving access to accurate test results.

Second, the Bayh-Dole Act, which sets rules for patenting the fruits of federally-funded research, gives the funding agency the right to "march-in" and grant compulsory licenses to ensure effective use of the technology or to benefit public health and safety. A significant percentage of patents to isolated genes are covered by this provision.

These case-by-case mechanisms for choosing between exclusion and a compulsory license are superior to an inflexible rule that precludes all patents on all isolated, useful genes. They ensure patent rights are tailored to the public interest without jeopardizing private investment in life-saving technology.

ARGUMENT

I. Isolated Genes With a Specific, Substantial, and Credible Utility Should Be Patentable.

A. The Legal Framework

The task of separating a patent-eligible "composition of matter" under § 101 from an unpatentable product of nature is a difficult one. All human invention, particularly in biology, starts by building upon nature's materials and laws. "Everything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.'" *Funk Brothers Seed Co. v. Kalo Co.*, 333 U.S. 127, 135 (1948) (Frankfurter, J., concurring). "Only God works from nothing. Men must work with old elements." *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 n.3 (Fed. Cir. 1985). So when has there been enough human intervention to make the resulting composition patent-eligible? I respectfully submit that threshold is crossed whenever a composition has a specific, substantial, and credible utility different from what is found in nature.

There is a long history of using utility to distinguish between the patent-eligible and ineligible. Judge Learned Hand held, over a century ago, that a patent covering isolated human adrenaline was a patent-eligible "composition of matter" based on the distinct utility of the isolated compound. *See Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911). He explained that the patentee "was the first to make it available for any use by removing it from the other gland-tissue in which it is found and . . . it became for every practical purpose a

new thing commercially and therapeutically. That was a good ground for a patent." *Id.*

This Court's cases have likewise looked to utility when assessing patent-eligibility. In *Funk Brothers*, the Court observed that "[h]e who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law to a new and useful end." *See* 333 U.S. at 130. The Court then found that a mixture that combined several naturally occurring bacteria was unpatentable in part because it produced "no enlargement of the range of their utility." *Id.* at 131.

By contrast, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), dealt with my discovery that I could transfer multiple "plasmids" that controlled a bacterium's ability to degrade various components of crude oil into a single *Pseudomonas* bacterium that had no pre-existing capability to degrade oil. *Id.* at 305 & nn.1-2. The result was a stable and harmless bacterium with a new utility for degrading oil that had not existed before. *Id.* The Court held that my genetically-engineered bacterium was patent-eligible in part because of its "potential for significant utility." *Id.* at 310. And the Court distinguished the discussion in *Funk Brothers* that had relied on the lack of new utility to deny patent eligibility there. *Id.* Even though I had used natural materials to build my invention, the Court found it patent-eligible based on its new, significant utility.

Finally, the text of § 101 itself suggests using utility as a dividing point, stating that "[w]hoever invents or discovers any new and useful . . . composition of matter" shall be eligible for a patent. *See* 35

U.S.C. § 101. A substance that is isolated out of its natural state via a structural and functional change to the substance is "new," and, if the composition also possesses a unique utility, it is "useful" in a way that the naturally-existing thing was not. Assessing patent-eligibility without reference to whether the isolated composition possesses a unique utility would read the phrase "new and useful" out of § 101. Imposing additional requirements beyond some change from the natural structure and a specific utility would improperly read a requirement into the text of § 101 that is not there.

This Court's concerns about patents on laws of nature are squarely addressed by using utility as a touchstone of patent-eligibility. If only compositions with a new, specific utility are patent-eligible, then patent protection will be limited to applications of nature's building blocks, rather than the building blocks themselves. A "utility test" also ensures that patents are available to serve their primary function—ensuring that inventors invest in useful technologies and bring them to market—without tying up what has not yet been put to use and thereby preventing others from finding such a use.

The extent of the structural similarities and differences between what exists in nature and what is sought to be patented should not drive the analysis. Seemingly small structural changes to chemical and biological compounds often make an enormous difference in their function. Altering even a single nucleotide or amino acid in a gene or protein can make the difference between a therapeutically active molecule and a therapeutically inert one. Indeed, the genetically-engineered *bacterium* that I created and sought to patent in *Chakrabarty* had a quite similar

structure to what existed in nature. It shared the same genome and internal structure as naturally occurring *Pseudomonas* bacteria and differed only by a few pieces of DNA. But those small structural differences led to a new and significant utility that made the modified bacterium patent-eligible. If Petitioners' position that a composition must have "substantial" structural differences from what exists in nature to be patent-eligible, then I would never have obtained my patent in *Chakrabarty*.

B. The Patent-Eligibility of Genes

The legal principles just discussed yield several conclusions about the patent-eligibility of human genes. First, "wild-type" genes that exist in natural form should not be patentable because they have no special utility beyond the functions they already carry out in nature. Moreover, patent protection should not be extended to isolated genes that do not possess a specific, credible utility. Patents to such compositions would cover nothing but nature's building blocks because they would not impart any particular usefulness that was created by human intervention and manipulation. New, isolated genes that have a specific, substantial, and credible utility, however, should be patent-eligible.

The U.S. Patent & Trademark Office, when analyzing the patent-eligibility of human genes, reached these same conclusions. After an extensive notice and comment period, the agency issued guidelines in 2001 for examiners to apply when assessing patentability under § 101's "utility" requirement. *See* 66 Fed. Reg. 1092 (Jan. 5, 2001). Some of the public comments urged the agency "not to issue patents for genes on the ground that genes are not inventions," *id.* at 1092, the same argument Petitioners make

here. The agency rejected this argument and adopted the position I am advocating here, providing the following explanation:

> If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the "utility" requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.

Id. at 1093. The agency cited, among other things, Judge Hand's decision in *Parke-Davis* as support for its conclusion. The Guidelines, which are the work of an agency with specialized expertise in this area, have been consistently applied for over a decade. They have strong persuasive force here.

Applying these principles, the Myriad patent claims that cover isolated DNA with the *BRCA1* and *BRCA2* mutations associated with an increased risk of breast or ovarian cancer should be patent-eligible because they have a specific, substantial, and credible utility. Locating and characterizing both the genes and the genetic mutations involves significant human effort. Once the mutations are isolated, they can be used to determine whether a woman is predisposed to these types of cancer, and to screen potential drug candidates to fight the cancer as it emerges or to prevent it from ever starting. These uses for the isolated genes with the relevant mutations would not exist without the inventors' efforts.

And they are different than what DNA is used for in nature, which is to store information and direct protein synthesis.

Indeed, a collection of federal agencies applying the Affordable Care Act recently confirmed the utility of Myriad's testing. The Act requires that all non-grandfathered private insurance plans cover, without imposing any cost-sharing, a list of preventive services to be determined by the U.S. Preventive Service Task Force. *See* 42 U.S.C. § 300gg-13. Both Myriad's genetic counseling and its actual testing for the mutation are now included as a preventive service covered by this provision. *See, e.g.*, *BRCA Testing Granted Preventive Care Designation Under the Affordable Care Act,* http://tinyurl.com/b9y5boa (last visited Mar. 14, 2013). As a result, "women who are members of non-grandfathered insurance plans, who are determined to be high risk by their healthcare providers, will have no out-of-pocket costs including copays, deductibles, and coinsurance when ordering" Myriad's testing. *Id*. Not only does this show that Myriad's testing will be widely available, it demonstrates that the relevant agencies with expertise have recognized the usefulness of Myriad's testing. And that testing is made possible only by Myriad's isolation of the BRCA mutations. This is the same sort of real-world application this Court has held confers patent-eligibility. *See Diamond v. Diehr*, 450 U.S. 175 (1981) (holding the application of the Arrhenius equation to a process of curing rubber is patent-eligible under § 101).

There is more. Myriad's patented *BRCA1* and *BRCA2* mutations have another exciting new, specific use: identifying women who could benefit from new anti-cancer therapies. A young woman who

tests positive for the mutation currently faces a devastating choice—should she live in fear knowing that she will probably develop cancer, or should she immediately have her breasts and reproductive organs surgically removed to eliminate the risk of cancer? I, along with others in the field, am working toward a better option.

We have recently demonstrated that a bacterial protein (azurin), and a peptide derived from it (p28), were able to selectively enter and kill human cancer cells while not attacking healthy cells. Although azurin has not yet been clinically tested, p28 showed significant beneficial effects in Phase I clinical trials involving 15 patients with Stage IV cancer, which is the most advanced state. *See, e.g.,* Fialho & Chakrabarty, 13 CANCER BIO. & THER. at 1231, and references cited there. Not only is p28 free from any toxicity, but, in two patients, it showed significant beneficial effects, including complete regression of tumors that were resistant to all conventional drugs. *Id*. In separate laboratory experiments, we have demonstrated, and in fact patented, the additional role of p28 in preventing the onset of pre-cancerous lesions in mouse mammary cells. *See, e.g.,* U.S. Patent No. 8,232,244. We have thus clearly demonstrated that a potential candidate drug such as p28 not only does not demonstrate any significant toxicity, unlike most chemotherapeutic drugs, but also has both cancer therapeutic and cancer preventive activity. *Id*.

The screening for *BRCA1* and *BRCA2* mutations can be used to identify women who would be excellent candidates for additional research into the anticancer and cancer-preventive potential of p28. If women with the mutations who are taking p28 expe-

rience lower rates of cancer than are usually associated with the mutation, this would be strong evidence that p28 could be a successful treatment for ovarian and breast cancer, or could stop those cancers before they emerge. *Id.* Myriad's isolation of the *BRCA1* and *BRCA2* mutations can thus be applied to achieve a major breakthrough in treating breast and ovarian cancer patients for a possible permanent cure.

The unique utility of *BRCA1* and *BRCA2* mutations makes them different from the examples relied upon by Petitioners and Judge Bryson's dissenting opinion below to argue against patentability. A human kidney that has been removed (isolated) from the body does not have any utility apart from that which existed in nature. Neither does a polished diamond, nor gold taken from a stream, nor a leaf snapped from a tree. But the Myriad patents covering the isolated *BRCA1* and *BRCA2* mutations allow for genetic testing and drug screening for a permanent cure for cancer that would be impossible with non-isolated mutation-harboring DNA as it exists in the genome of a vulnerable woman. For that reason, they should be patent-eligible.

C. The Practical Consequences

There are significant real-world benefits to recognizing as patent-eligible any isolated gene with a specific, substantial, and credible utility. Consider what might have happened if patent protection for the *BRCA1* and *BRCA2* mutations were unavailable. Industry funding would have disappeared because there would be no guarantee that any investment into characterizing the mutation could be recouped. In the absence of patent protection, others could wait for an initial investor to characterize the mutations,

and then they could copy the technology and sell it to the public at a lower price that the original investor—who would be burdened with the large up-front R&D costs—couldn't match. As a result, there would never be an initial investor. Although there would still be government funding for such research, it would not cover the shortfall. Moreover, government funding would be directed mostly to universities, where fundamental basic research is conducted more for publications than for problem solving, and not to entities capable of commercializing the technology.

The possible results of this funding shortfall? Researchers may never have located the mutations. Myriad may never have been able to bring tests for the mutations to market. And researchers like myself may never have been able to use the mutations to identify patients who would benefit from new anti-cancer and cancer-preventive therapies.

Patent protection for isolated genes with a specific, credible utility not only drives technology to market, but it also encourages "the public disclosure of new and useful advances in technology," an important goal of patent law. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63, (1998). Those who isolate useful genetic mutations can currently disclose their findings to the public in a patent application while obtaining a limited window of protection that will enable them to recover their investments. Without the option of patent protection, companies that make major investments in insolating genetic mutations will have every incentive to keep their work a trade secret. *See, e.g.,* William M. Landes & Richard A. Posner, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 328-32 (2003). Such secrecy would divert resources away from the fight against cancer, as

companies would spend money protecting their information rather than re-investing in further research. *Id*. It would also lead to duplicated efforts, as multiple companies might repeat the same work, unable to build on one another's efforts or to diversify their efforts and each pursue different mutations. And it would impede others from using that research as a jumping off point to design new drugs that may be able to eradicate cancer altogether—as in the case of the p28 research discussed above.

Myriad's patents are not alone in having enabled a company to bring technology to market. DNA-related patents have led to many new medical treatments that would not have existed without patent protection. One early success was Genentech's use of recombinant DNA—*i.e.,* human-made DNA synthesized by piecing together natural material from multiple sources—to direct microorganisms to produce insulin. *See, e.g.,* U.S. Patent No. 4,704,362, and others in the portfolio. Genentech licensed the patents to Eli Lilly, which used the technology to market the first form of synthetic human insulin, a drug called Humulin. Lilly began selling the product in 1982, and it quickly proved to be superior to the existing animal insulin products, all of which were more likely to produce an allergic reaction. *See, e.g.*, Irving S. Johnson, *Human insulin from recombinant DNA technology*, 219 SCIENCE 632 (1983) (describing the history). By 2006, human insulin or insulin analogs had replaced animal insulin products in the United States. *See, e.g., Insulin,* http://www.diabetesdaily.com/wiki/Insulin (last visited Mar. 14, 2013.). These achievements would not be possible without patent protection, which ensured that Genentech and Lilly recouped their significant investments in bringing this technology to market.

Whatever the Court does in this case, it should avoid broad pronouncements that render entire categories of patents invalid. If the Court were to simply answer the question "are human genes patentable" with a categorical "no," it would, to be sure, eliminate some bad patents. But, if the Court were to extend this answer to even patents involving isolated genes or recombinant DNA—which are not the same as "human genes" as they exist in nature—it would also eliminate many good patents, like Genentech's and Myriad's, which have led to medical testing and treatments that would not otherwise have been available.

There are many different types of gene patents, and the patent-eligibility of each should be analyzed on its own merits. Relying on "specific, substantial, and credible utility" as the test of patent-eligibility would give the courts the flexibility to do this. And it would ensure that good patents covering useful results are permitted while bad patents that lock up nature's building blocks before they can be put to use are prohibited.

II. The Law Already Provides Mechanisms for Compulsory Licensing of Gene Patents.

The briefs of Petitioners and some other *amici* (including Dr. James Watson) suggest broadly that permitting patents on isolated human genes with a specific utility will prevent anyone else—*e.g.*, university researchers, clinicians, and other testing laboratories—from using those genes. But, in fact, a patent does not always give its owner the right to exclude others from using the patented invention. Existing law provides multiple mechanisms by which one can obtain a compulsory license to a patent.

For one thing, this Court held in *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006), that injunctions in patent cases are not automatic. Instead, a patentee seeking an injunction must prove, among other things, that "the public interest would not be disserved" by an injunction. *Id.* at 391. The lower courts, applying *eBay*, have not hesitated to deny injunctions where they disserve the public interest, including the interest in health and safety. *See, e.g., Johnson & Johnson Vision Care, Inc., v. CIBA Vision Corp.*, 712 F. Supp. 2d 1285 (M.D. Fla. 2010); *Bard Peripheral Vascular, Inc. v. WL Gore & Assocs., Inc.*, 2009 WL 920300 (D. Ariz. March 31, 2009); *Advanced Cardiovascular Sys. v. Medtronic*, 579 F. Supp. 2d 554 (D. Del. 2008). So all of the concerns that Petitioners and other *amici* raise about a patient's ability to get a second opinion, the ability of other researchers to identify different mutations or alternate ways of using the claimed mutation, and the like, could be addressed in a case-specific context by the district court in deciding whether to enjoin any of that activity.

After *eBay*, the Federal Circuit had to address what should happen in cases where an injunction does not issue. That court held that, when an injunction is denied, the district court may allow the defendant to continue to use the patented technology if it pays an ongoing royalty to the patent holder. *See Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1313-16 (Fed. Cir. 2007). This is, in effect, a compulsory license. Although the standards for determining the appropriate royalty rate are in flux, district courts now routinely impose compulsory licenses in cases where an injunction is denied. *See, e.g., Boston Scientific Corp. v. Johnson & Johnson*, 2009 WL 975424 (N.D. Cal. Apr. 9, 2009); *Orion IP, LLC v.*

Mercedes-Benz USA, LLC, No. 05-cv-322, Doc. 638 (E.D. Tex. Mar. 28, 2008). So if the district court found that an injunction was not in the public interest based on one of the concerns articulated by Petitioners and other *amici*, it could impose a compulsory license at a rate appropriate to compensate the patentee, but low enough to ensure that "infringing" activity deemed to be in the public interest could continue. For some types of non-commercial activity that pose little harm to the patentee, like academic research, the royalty rate would likely be close or equal to zero.

For another thing, when patents result from federally-funded research, the funding agency can "march-in" and grant a compulsory license to the patent in several situations. *See* 35 U.S.C. § 203(a). Those situations include cases in which "action is necessary to alleviate health or safety needs which are not reasonably satisfied by" the patentee, *id*. at § 203(a)(2), or where the patentee "has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use." *Id*. at § 203(a)(1). The funding agency presumably possesses specialized expertise about the technology covered by the patent and whether a license is necessary to protect the public interest.

These march-in rights are particularly significant for patents to isolated human genes. Many DNA patents are owned by universities that obtained them through federally-funded research. One article reports that non-profit institutions owned between one-third and one-half of all DNA patents that issued from 1980-2003. *See* Robert Cook-Deegan & Christopher Heaney, *Patents in Genomics and Human*

Genetics, 22 ANN. REV. GENOMICS HUM. GENETICS 383 (2010). Another study, relying on data through 2005, found that 13 of the 30 entities holding the most DNA patents were non-profit universities. *See* Lori Pressman, et al., *The Licensing of DNA Patents by Large U.S. Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECHNOLOGY 31, 33 (2006). The study also found that the government had an interest in 50% of DNA patents owned by the top 30 academic institutions, and had an interest in 13.7% of all DNA patents. *Id*. at 36. And, indeed, the patents at issue in this case are owned by the University of Utah and resulted from research that was sponsored in part by the National Institutes of Health. *See* 702 F. Supp. 2d 181, 202 (S.D.N.Y. 2010).

These mechanisms show that making isolated human genes eligible for patent protection will not exclude others from using them for all purposes. Instead, a district court or the funding agency (or both) has discretion to assess, on a case-by-case basis, whether exclusion is the appropriate remedy, or whether damages alone will suffice. Flexibility will lead to more informed decision-making, as the court or agency will be able to consider the evidence on the specific patent before it and determine the appropriate remedy for any infringement.

This Court has endorsed such flexibility in patent law, eschewing categorical rules in a variety of contexts, including § 101. *See, e.g., Bilski v. Kappos*, 131 S.Ct. 3218 (2010) (declining to hold that business method patents are categorically ineligible for patent protection); *KSR v. Teleflex Co.*, 550 U.S. 398 (2006) (rejecting the rigid teaching, suggestion, or motivation test for obviousness); *eBay*, 547 U.S. at 391-94 (holding there is no presumption that an injunction

should issue). A similar approach is appropriate here. By contrast, a sweeping pronouncement that no isolated genes are eligible for patent protection would upset existing expectations, discourage future investment, and could slow or prevent countless new inventions in this promising area of technology. This Court's usual case-by-case approach to crafting rules of patent law is the far better one here.

CONCLUSION

For the reasons above, *amicus* encourages the Court to hold that isolated human genes with a specific, substantial, and credible utility, such as those covered by the Myriad patents, are patent-eligible under § 101.

Respectfully submitted,

CRAIG E. COUNTRYMAN
Fish & Richardson P.C.
12390 El Camino Real
San Diego, CA 92130
(858) 678-5070

JONATHAN E. SINGER
Counsel of Record
Fish & Richardson P.C.
3200 RBC Plaza
60 South Sixth Street
Minneapolis, MN 55402
(612) 335-5070

Counsel for *Amicus Curiae*