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 JAMES D. WATSON, PH.D. AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

MATTHEW J. DOWD
Counsel of Record
JAMES WALLACE
WILEY REIN LLP
1776 K Street, NW
Washington, D.C. 20006
(202) 719-7343
mdowd@wileyrein.com

Counsel for Amicus Curiae

245815

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

TABLE OF CONTENTS

TABLE OF CITED AUTHORITIES

Page

CASES

CONSTITUTION

OTHER SOURCES

Cited Authorities

Page

INTEREST OF *AMICI CURIAE*[1]

Amicus curiae James D. Watson, Ph.D., is the co-discoverer of the double helix structure of deoxyribonucleic acid ("DNA"). For this discovery, he and his colleague, the late Francis Crick (along with the late Maurice Wilkins for related work), were awarded the Nobel Prize in Physiology or Medicine in 1962. *See* James D. Watson, *The Double Helix* (1968).

Throughout his career, Dr. Watson has been at the forefront of recombinant DNA research and advances in genetic engineering. From 1956 until 1976, Dr. Watson was on the faculty of Harvard University, leading the effort to focus the biology department on the then-emerging field of molecular biology. Starting in 1968, Dr. Watson was the director of Cold Spring Harbor Laboratory ("CSHL"). From 1994 to 2004, he served as the president of CSHL, and from 2004 until 2007, he was CSHL's Chancellor. Dr. Watson is now Chancellor Emeritus of CSHL.

Dr. Watson's current research relates to the causes and potential cures of cancers. His interest in cancer first publicly expressed itself through his teaching on tumor viruses after he joined the Harvard University Biology Department in the fall of 1956. At that early stage, his

1. The petitioners have filed a letter of blanket consent to *amici* on January 2, 2013. Respondents granted consent to *amicus* on January 9, 2013, via electronic mail, a copy of which is being submitted herewith. *Amicus* and his counsel represent that no party to this case nor their counsel authored this brief in whole or in part, and that no person other than *amicus* paid for or made a monetary contribution toward the preparation and submission of this brief.

lectures explored how cancer might be induced by DNA tumor viruses, the smallest of which probably had DNA sufficient to code for only 3–5 proteins. His expertise with recombinant DNA and cancer research lends particular insight into the case at hand, which concerns the patentability of human genes relating to breast cancer.

The author of numerous books and research articles, Dr. Watson has received several honors for his scientific research, including the Albert Lasker Prize (1960), the Nobel Prize in Physiology or Medicine (1962), the John J. Carty Gold Medal of the National Academy of Sciences (1971), the Presidential Medal of Freedom (1977), the Copley Medal of the British Royal Society (1993), the Lomonosov Medal, Russian Academy of Sciences (1995), the National Medal of Science awarded by the National Science Foundation (1997), the University of Chicago Medal (1998), the New York Academy of Medicine Award (1999), the University College London Prize (2000), the Benjamin Franklin Medal for Distinguished Achievement in the Sciences (2001), and an Honorary Knighthood of the British Empire (2002).

Of particular relevance to the question presented to the Court is Dr. Watson's role in the Human Genome Project and his career-long involvement with recombinant DNA research. Dr. Watson was one of the earliest proponents of sequencing the human genome. In 1988, Dr. Watson was appointed Associate Director for Human Genome Research at the National Institutes of Health ("NIH") and, in 1989, Director of the National Center for Human Genome Research at the NIH. In these positions, Dr. Watson initiated and led the public effort to sequence the human genome. Even at that time, the question of whether human genes should be patented was one of critical importance.

Given the importance of the question presented, Dr. Watson presents his arguments from his personal, unique perspective on the issue of whether human genes are patentable.

* * *

SUMMARY OF THE ARGUMENT

Human genes should not be patented. *First*, a human gene is fundamentally unique—unlike any ordinary "composition of matter." A gene conveys information—the instructions for life. As a product of nature, a human gene's primary purpose is to encode the information for creating proteins, enzymes, cells, and all the other components that make us who we are. I explained much of this when I submitted my amicus brief to the appeals court, but that court was unpersuaded. So I reiterate what I told the appeals court: Life's instructions ought not be controlled by legal monopolies created at the whim of Congress or the courts.

Second, much of what we now know about human genes traces back to the Human Genome Project, which was structured as a public works project, intended to benefit everyone by deciphering our genetic code. Our goal was to construct a map of what already existed in nature, namely our genes. Accordingly, I, along with other prominent scientists, expressed the strong opinion that human genes should not be patented. There was simply no need for it. Others, including some at the National Institutes of Health, disagreed. Eventually, much but not all of the human genome was dedicated to the public through the efforts of the Human Genome Project. It was

a mistake by the Patent Office to issue patents on human genes and a mistake by those who filed for those patents.

Third, human gene patents are not necessary to encourage scientists to advance our knowledge and develop innovative new medicines or biotechnology inventions. The important innovations needing patent protection are not the human genes themselves but the technologies that use human genes. And here, it is important that the human genes can be reasonably accessible so that as many top minds as possible can develop the new technologies based on the human genes. As you read this, scientists are creating new procedures using hundreds, if not thousands, of genes for diagnosing and treating life-threatening diseases, including breast cancer. Innovation will be rewarded based on those developments, not the patenting of the human gene. Thus, if it were decided that human genes can be patented, courts should grant compulsory licenses. Such licenses would ensure access to human genomic information on reasonable terms, guaranteeing that our genomic map creates the most benefit for mankind.

ARGUMENT

I. Because Human Genes Are Unique And Convey Information About The Essence of Being Human, They Should Not Be Patented

I have read through the various opinions issued in this case.[2] The opinions admirably describe the scientific

2. I have also read the Supreme Court's decision in *Mayo v. Prometheus*, although its opaqueness must leave many attorneys wondering if it adds anything at all to the issue of whether human genes ought to be patented.

details of DNA and human genes, but the opinions by the appeals court miss the fundamentally unique nature of the human gene. Simply put, no other molecule can store the information necessary to create and propagate human life the way human DNA does. It is a chemical entity, but DNA's importance flows from its ability to encode and transmit the instructions for creating a human being.

The question presented to this Court is one which, I believe, requires an appreciation of the history of human DNA research. The appeals court appeared not to fully appreciate this history and how it necessarily informs the inquiry. Moreover, Congress has not enacted any specific law which says that human genes are patentable. Indeed, the nature of the gene—and the double-helical structure of DNA on which genes are encoded—mandate that a human gene does not fall within the ordinary meaning of "composition," as Congress set forth in the 1952 Patent Act.

Even before DNA's structure was revealed, many scientists recognized the importance of a cell's chromosomes (which are composed of DNA) to the propagation of life. In 1944, Erwin Schrödinger, a Nobel Prize-winning physicist, wrote a small book titled *What Is Life?* In it, he reasoned that chromosomes were the genetic information bearers. Schrödinger thought that, because so much information must be packed into every cell, the information must be compressed into "hereditary code-script" embedded in the molecular fabric of the chromosomes. The same year, Oswald Avery, Maclyn McCarty, and Colin MacLeod provided empirical proof that DNA was the genetic material. Even so, many skeptical scientists questioned this finding, until 1952, when Alfred Hershey and Martha Chase laid to rest any

doubts with their experiments done at Cold Spring Harbor Laboratory.

The secret to DNA's ability to create life is its double helical structure, along with its information-coding sequences. Francis Crick and I published the first correct structure of DNA in 1953. J.D. Watson & F.H.C. Crick, *A Structure for Deoxyribose Nucleic Acid*, 171 Nature 737 (1953). Building on the X-ray crystallographic work of Maurice Wilkins and Rosalind Franklin, Francis and I determined that DNA forms a double helix. At the time, we were in a tight race with Linus Pauling (soon to be a Nobel laureate in chemistry and later a laureate for the Peace Prize). Fortunately for us, Pauling concluded that DNA was a triple helix—an erroneous conclusion ironically based on a chemical error made by a most-brilliant chemist.

The double-helical structure of DNA epitomizes elegance in simplicity. From a chemical perspective, DNA is a simple compound, little more than two strands of a nucleotide polymer wound together in a double-helix formation. The nucleotide polymer consists of various sequences of A, T, G, and C bases. The two strands of the double helix are complementary to each other.[3]

When Francis and I deciphered the structure, we immediately understood its significance. With a hint of more to come, we wrote in our article that "[i]t has

3. Amusingly, after I gave my first presentation of our DNA structure in June 1953, Leó Szilárd, the Hungarian physicist and an inventor of the nuclear chain reaction, asked whether I would patent the structure. That, of course, was out of the question.

not escaped our notice that the specific pairing we have postulated immediately suggests a possible copying mechanism for the genetic material." *Id.* The double-helix structure confirmed DNA's role as the genetic carrier and created the possibility of almost limitless information storage. The various sequences of bases could be translated by a cell's machinery, and that information would be used to create new proteins for the cell. Following physicist George Gamow's suggestion, Sydney Brenner and Francis Crick later demonstrated that the smallest informational unit, the codon, was three bases long, *e.g.*, AAA, TTT, etc.

Later scientists discovered that certain DNA sequences controlled the expression of other genes. One of the earliest of these control sequences discovered was the "TATA box." The TATA box contains the core DNA sequence 5'-TATAAA-3' or a similar variant. Specific proteins can bind to this sequence, which promotes the transcription of other specific genes. Extracted from the chromosome, a nucleic acid molecule having the TATAAA sequence has little, physically inherent value. Its significance arises because that sequence is useful information to the cell's genetic machinery. The TATAAA sequence leads to the expression of genes that affect the cell and ultimately our human experience.

The terminology of molecular genetics underscores DNA's informational role in life. In a living cell, DNA is used to make RNA, and then RNA is used to make polypeptides, *i.e.*, protein. The first step—DNA to RNA—is called "transcription." The second step—RNA to proteins—is called "translation." Both words connote the conveyance of information instead of simply the

creation of new chemical entities, and for good reason. The information encoded by a human gene is first *transcribed* into RNA (DNA and RNA are similar molecules, thus similar languages, so the genetic information is merely transcribed from one format to another). Then, the genetic information is *translated* from RNA into protein. (RNA and protein are different biochemical "languages," hence translation). The entirety of the DNA machinery relates to transferring and utilizing the genetic information.

When cells replicate, they make copies of the genetic code for the progeny cells. New strands of DNA are synthesized in a process analogous to the way scriveners of years past would copy legal documents. Just as scriveners would copy legal documents word by word, a cell copies the DNA molecule letter by letter (A, T, G, or C). And just as scriveners proofread their work, the DNA polymerase—the enzyme that replicates DNA—has a built-in proofreading mechanism. But as with all proofreading, the system is not perfect, and errors occur. "Typographical" errors with DNA replication can lead to genetic mutations—which can cause devastating diseases or can lead to evolutionary improvements.

To this day, we continue to learn how human genes function. We estimate that humans have approximately 21,000 genes. We have yet to fully understand the functions of all human genes, but this lack of understanding is further reason that scientists should be permitted to experiment on human genes free from any threat of patent infringement.

The social history of human genes also reveals the unique informational component of human DNA that sets

it apart from other chemical compounds. In the early part of the twentieth century, many in society believed that the answers to all of society's ills resided in the human genome. From that belief grew the ill-fated eugenics movement, founded on an incomplete understanding of human genetics.

Even the esteemed Justice Oliver Wendell Holmes, along with some of his colleagues, misunderstood the role of genes in human development. In the landmark case of *Buck v. Bell*, 274 U.S. 200, 207 (1927), Justice Holmes expressed a view about genetics that prevailed during his time:

> It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. . . . Three generations of imbeciles are enough.

We now know that many factors affect a person's mental acuity, genes being some of them. But Justice Holmes and other supporters of the eugenics movement could not appreciate, at that time, the precise role of how genetics determines and influences a person.

In years to come, with the right advances in genetic engineering, we may well be able to treat or rectify mental disabilities and physical diseases which today are deemed incurable. Such hope is all the more reason that scientific research on human genes should not be impeded by the existence of unnecessary patents. More importantly, we would not want one individual or company to monopolize

the legal right to the beneficial information of a human gene—information that should be used for the betterment of the human race as a whole.

By the 1970s, the public's perception of DNA and genetic technology had reached its nadir. Far from being viewed as the vindicator of the wrongfully accused—as the public often sees it today—recombinant DNA technology was considered by many to be inherently dangerous. In fact, various interest groups wanted to ban recombinant DNA research.[4] Ironically, this hysteria seemed to begin after I participated in the first scientific discussions exploring whether proposed regulations on DNA research were necessary (at the Gordon Research Conference of Nucleic Acids in June 1973).

Unfortunately, the initial ruminations mutated into full-fledged proposed restrictions, issued from the Asilomar Conference in February 1974. Later, in the summer of 1976, as the hysteria increased, the National Institutes of Health ("NIH") published guidelines governing recombinant DNA research. Shortly after, the public discourse reached such a fevered pitch that, in the summer of 1976, the Cambridge City Council declared a three-month moratorium on all recombinant DNA research in the city of Cambridge—and therefore at Harvard University and the Massachusetts Institute of Technology. These decisions had significant consequences, in some cases forcing scientists to abandon and discard the results of their experimental research.

---

4. I recount much of this history in one of my books. *See* James D. Watson & John Tooze, *The DNA Story: A Documentary History of Gene Cloning* (1981). Another good article is Michael Rogers, *The Pandora's Box Congress*, Rolling Stone, June 19, 1975, at 36, which is reprinted in *The DNA Story*.

Congress also joined the bandwagon of trying to regulate recombinant DNA research. In the fall of 1976, the late Senator Edward Kennedy, as chair of the Senate Health Subcommittee, conducted hearings on whether Congress should enact legislation restricting recombinant DNA research. Some in Congress even wanted to ban the research.

I, of course, did not favor these restrictions. I explained at the time that "our Congressmen are being asked to decide between two silly alternatives." J.D. Watson, *In Defense of DNA*, The New Republic, June 25, 1977, at 11. At one point, I had to defend recombinant DNA research from the attacks of the actor Robert Redford, who, along with the Environmental Defense Fund, raised money hoping to halt basic research experiments using recombinant DNA. *See* James D. Watson, *The Nobelist vs. The Film Star: DNA Restrictions Attacked*, Washington Post, May 14, 1978, at D1. Other prominent scientists, including but not limited to Joshua Lederberg and Stanley Cohen, were vocal in their defense of recombinant DNA research. Eventually, reason and objectivity prevailed, NIH loosened its guidelines, and Congress refrained from enacting detrimental legislation. Scientists were again free to conduct their recombinant DNA research without absurd restrictions.

My point with this overly brief and incomplete history of the early days of recombinant DNA research is to illustrate how those major controversies associated with human genes arose because human genes are much more than chemical compounds. The myopic perspective thinks of a human gene as merely another chemical compound—another composition—consisting of various bases and

sugars wrapped together in a double helix. Science and history teach us otherwise, however.

During the height of the hysteria, a popular columnist for the San Francisco Chronicle asked, "Why will scientists persist in playing God?" *See* James D. Watson & John Tooze, *The DNA Story: A Documentary History of Gene Cloning* 165 (1981) (reprinting Charles McCabe, *On Playing God*, San Francisco Chronicle, Apr. 4, 1977). We were not playing God, but that is what many people thought—not because of who we were but because we were working with the instructions for creating human life.

Human genes—quintessential products of nature—are useful because they convey vital information. The human genome's ability to be our instruction book on life distinguishes human DNA from all other chemicals covered by the patent laws. No other molecule carries the information to instruct a human zygote to become a boy or a girl, a blonde or brunette, an Asian, African, or Caucasian.

Some may suggest that all the above has little relevance to whether human genes are patentable. But that suggestion ignores the important social consequences of restricting the use of human genes. Our history confirms that a human gene is not just another chemical compound. A human gene is a product of nature and is more than simply a fragment of a longer DNA polymer. A human gene's patentability cannot depend simply on whether a covalent bond is broken during purification. Human genes—unlike any other chemical composition—reveal information that can be important in life-or-death situations. The information contained in our genes lets

us predict our future. With a gene sequence in hand, we can know with some degree of certainty whether we will develop cancer, a neurological disease, or some other malady. This information should not be monopolized by any one individual, company, or government.

II. The Human Genome Project Was Intended To Benefit All, Not Just Select Companies

In addition to understanding the uniqueness of human DNA, an awareness of the Human Genome Project's history should guide the Court to the correct decision that human genes, as products of nature, should not be patented. The Human Genome Project was started not to increase the profits of select companies but to expand our understanding of the human genome and make this information available to all scientists. To permit patent monopolies on human genes would contravene the spirit of the multinational, taxpayer-subsidized, public works effort to sequence the human genome.

The genesis of the Human Genome Project dates to the mid-1980s, when the dual technological advances of recombinant DNA and computers opened the door to deciphering the human genome. In June 1986, I organized a special session at Cold Spring Harbor Laboratory to discuss the beginnings of what would become the Human Genome Project. At that time, the U.S. Department of Energy had also begun to focus on sequencing the genome. Other eminent scientists joined the early effort, including but certainly not limited to Bruce Alberts, Sydney Brenner, and David Botstein. Eventually, we published our report (from the National Academy of Sciences) making the case for sequencing the human genome. With

the support of James Wyngaarden, then-head of NIH, and many others, the Human Genome Project became a reality.

In May 1988, I was appointed Associate Director for Human Genome Research of NIH (and later, in 1989, became NIH's Director of the National Center for Human Genome Research). In these positions, my role was to oversee a multimillion-dollar budget and to organize what had become a multi-agency, international effort to decipher the human genome. The United States directed the project and carried out half of the work, while the rest was done mainly in the United Kingdom, France, Germany, and Japan.

Even at the early stages of the project, we were concerned about the issue of patenting human genes. Most, although not all, eminent scientists recognized that human genes should not be monopolized by patents. I believed at the time—and continue to believe—that the issue of patenting human genes went to the very crux of whether the information encoded by human DNA should be freely available to the scientific community and the public at large. Some twenty years ago, I explained that patenting human genes was lunacy, and I was not a lone voice.

Sadly, and to the detriment of scientific research, my view did not control the policy decisions of NIH, which had filed for numerous patents covering human genes. Even more egregious were the types of patents being filed on human genes. Many of NIH's patents described only small fragments of genes and other unknown sequences of the human genome. In June 1991, an NIH official had urged Craig Venter, who at the time was working at NIH,

to file patent applications on several hundred new DNA sequences, even though, in many instances, neither Venter nor NIH had any inkling of what those sequences did. The following year, Venter listed over 2,000 more sequences in his patent applications, still having no clue about the function of those sequences. It was preposterous to grant patents on genes, fragments of genes, random bits of human DNA, and who knows what else when the scientists themselves had no clue as to what the DNA sequences did.

I expressed my objections to NIH management, but to no avail. To me, it was clear that the purpose of the Human Genome Project was to map and publish the human genome sequence for the scientific community. It was not to provide raw data to individual companies seeking government-backed exclusivity on the genetic code. As the then-leader of the project, I felt a particular obligation to do what I could. In my view,

> [t]he Human Genome Project is much more than a vast roll call of As, Ts, Gs, and Cs: it is as precious a body of knowledge as humankind will ever acquire, with a potential to speak to our most basic philosophical questions about human nature, for purposes of good and mischief alike.

James D. Watson, *DNA: The Secret of Life* 172 (2003). In 1992, I publicly opposed NIH's decision to patent human genes. As a result, I was left with no choice and therefore resigned from NIH that year.

By that time, the Project was well underway, and I felt comfortable that my departure would not have a negative effect. Notably, patenting human genes was not necessary

to complete the Human Genome Project. Indeed, the international effort was proceeding on schedule without any need to file patent applications on human genes. Fortunately, my successor, Francis Collins, had the good sense to understand that gene patenting was not necessary and inhibited fundamental research. He later explained that "[t]he information contained in our shared instruction book is so fundamental, and requires so much further research to understand its utility, that patenting it at the earliest stage is like putting up a whole lot of unnecessary toll booths on the road to discovery." Francis Collins, *The Language of Life: DNA and the Revolution in Personalized Medicine* (2010).

Less than fifteen years after its start, the Human Genome Project, along with Celera Genomics, achieved success. On June 26, 2000, President Bill Clinton and Prime Minister Tony Blair announced that the two groups had finished a working draft, which was published for the public in February 2001. Gaps in the rough draft were filled in by 2003—fifty years after Crick and I published the structure of DNA. Scientists have used the data to estimate that humans have approximately 21,000 genes—in some sense a surprisingly small number compared to other organisms.

The Human Genome Project was a multi-agency, international effort. It was funded in large part by taxpayer money, and the primary expectation was that the information derived from the sequenced human genes would be available for all scientists to use. Unfortunately, a decade later, private companies are still trying to unnecessarily restrict access to human genes and the information encoded in those genes. This situation burdens

all of society. Other scientists involved in the Human Genome Project continue to warn about the harms caused by patenting human genes. John Sulston, who received the 2002 Nobel Prize in Physiology or Medicine, headed the British effort of the Human Genome Project. He has explained that "many human genes have patent rights on them and this is going to get in the way of treatment unless you have a lot of money." *See* Alok Jha, *Human Genome Project Leader Warns Against Attempts to Patent Genes*, The Guardian, June 24, 2010, at http://www.guardian.co.uk/science/2010/jun/24/ human-genome-project-patent-genes.

Fortunately, much of the human genome was placed in the public domain. The Human Genome Project made efforts to ensure that gene sequences were published as soon as possible. The publication of the sequence limited the number of patents on human genes. Nonetheless, private entities, the NIH, and other entities have obtained patents on some of these genes. Eventually, the problem will disappear, as those patents expire. But in the interim, the Court should rule that human genes, as products of nature, are not patentable.

III. Human Gene Patents Are Not Necessary, But If They Are Granted, Compulsory Licenses Should Be Granted To Ensure Fair Access

In general, lawyers and judges misunderstand scientific research when they contend that patent protection is necessary to encourage scientists to discover human genes. A scientist does not—and should not—expect to obtain a legal monopoly over the information encoded by human genes. And the average scientist should

not expect a windfall simply for revealing the sequence of DNA bases that encode various genes. Research on human genes is one of those rare endeavors which should be—and is—done with the understanding that, although inventions based on those genes may later be commercialized, the genes themselves are to be employed for the maximum benefit of humankind.

Consider also whether a biotechnology or pharmaceutical company derives major revenue from the sales of human genes. From what I have seen, the answer is generally no. Most biotechnology and pharmaceutical companies do not derive much, if any, revenue from selling or licensing human genes. Rather, their primary revenue comes from products and services, such as pharmaceutical drugs or research tools, that might be based on human genes. The Court should not be overly concerned that banning patents on human genes will cause a detrimental loss of revenue.

Patenting human genes also deters and obstructs advances in genetic technologies that require the use and evaluation of multiple genes. For instance, investigators at the University of Washington have developed parallel gene sequencing methods for identifying inherited mutations in breast and ovarian cancer genes. *See* Tom Walsh, et al., *Detection of Inherited Mutations for Breast and Ovarian Cancer Using Genomic Capture and Massively Parallel Sequencing*, 107 Proceedings of the National Academy of Science USA 12,629 (2010). This group's approach uses multiple genes, not just the specific BRCA1 and BRCA2 genes in the Myriad patents, to estimate cancer risk.

My own recent investigations have highlighted the complicated genetic basis of human diseases. For

instance, complete genome sequencing is advancing our understanding of complex neurological diseases, such as schizophrenia, autism, Alzheimer's disease, and Parkinson's disease, to name just a few. *See* Huda Akil, et al., *The Future of Psychiatric Research: Genomes and Neural Circuits*, 372 Science 1580 (2010). It is becoming increasingly clear that the etiology of many neurological diseases will encompass multiple human genes, acting in concert.

Cancer research is also becoming increasingly dependent on a better understanding of the genetic mechanisms underlying the root causes of cancer. *See* Jim Watson, *Oxidants, Antioxidants and the Current Incurability of Metastatic Cancers*, 2013 Open Biology 120144 (Jan. 9, 2013). Specifically, it is imperative that "RNAi methodologies" be employed to identify the remaining major molecular targets for future anticancer drug development.

A human genome cluttered with no trespassing signs granted by the Patent Office inhibits scientific progress, particularly the development of useful tests and medicines in areas requiring multiple human genes. The resources devoted to cancer research, neurological diseases, and other areas will be diverted to concerns about whether one can use a particular human gene. For a new assay using hundreds of human genes, the sea of patents and patent applications would create hundreds, if not thousands, of individual obstacles to developing and commercializing the assay. The best way, in my view, to resolve this problem is to eliminate the unnecessary patenting of human genes.

If, for some reason, patents on human genes are deemed necessary, the next best, albeit imperfect, solution

is to require those patent holders to license the patents to other researchers so that scientific progress is not obstructed. This is often called a "compulsory license." In my view, a compulsory license can establish reasonable access to human genes and genetic information—which is what scientists in general want, had the lawyers and courts not complicated matters. Reasonable access facilitates scientific and social progress.

Compulsory licensing would ensure that scientists and the public will have reasonable access to human genes and genetic information. Compulsory licensing will attenuate the negative consequences of the genetic monopolies created by patents. Implementing a compulsory license protocol will also reduce the risk that a patient is denied access to life-saving medicines and technologies using human genes and the information encoded in the genes.

Companies and inventors should not fear the prospect of compulsory licensing of human gene patents. The inventors and investors would continue to receive an appropriate return on their inventions and investments. The upside will be that more researchers will have meaningful access to the essential tools for investigating and understanding the human genome. Best of all, compulsory licensing will diminish the frightening possibility that patients cannot get a second medical opinion. No patient should be subjected to single-source diagnostic testing of a potentially life-altering genetic condition. When viable alternative, gene-based diagnostics exist, a patent should not preclude the availability of those alternatives.

Finally, I do not suggest that all patents relating to recombinant DNA technology should be abolished or

denied. Scientists have developed many new and useful innovations based on recombinant DNA technology. In the 1970s, Herbert Boyer and Stanley Cohen started Genentech based on their pioneering work with recombinant DNA. Since then, countless companies have come and gone, advancing the state of the art for recombinant DNA and adding to the storehouse of knowledge along the way. Indeed, this Court itself has recognized that a genetically engineered bacterium—a man-made invention using recombinant DNA technology—can be a patentable invention. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

Scientists and companies will certainly continue their innovative efforts in the areas of personalized medicine, genome sequencing, recombinant DNA, and related areas. Before too long, it will cost less than $100 to sequence an individual's entire genome. Low-cost sequencing is set to revolutionize entire sectors of medical treatment. Scientists and inventors will continue to be rewarded for their innovations based on human genes. But governments have an obligation to ensure that these scientific advances are not thwarted or delayed by ill-informed policies restricting the use of the genes themselves.

Looking past the four words of the question presented, the ultimate inquiry is what decision will best promote scientific research on human genetics and medicine. That, after all, is what the Constitution requires when it authorizes patents that promote the progress of the "useful arts." U.S. Const. art. I, § 8, cl. 8. Indeed, as I have written before, "[g]ood patents, I would suggest, strike a balance: they recognize and reward innovative work and protect it from being ripped off, but they also make new technology available to do the most good."

James D. Watson, *DNA: The Secret of Life* 122 (2003). And when all is considered, patents on human genes are not good patents.

* * *

CONCLUSION

For the foregoing reasons, Dr. Watson respectfully submits that the Court should hold that human genes are a product of nature and therefore the information encoded by those genes cannot be monopolized by any single entity.

Respectfully submitted,

MATTHEW J. DOWD
Counsel of Record
JAMES WALLACE
WILEY REIN LLP
1776 K Street, NW
Washington, D.C. 20006
(202) 719-7343
mdowd@wileyrein.com

Counsel for Amicus Curiae