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

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TABLE OF CONTENTS

Page

TABLE OF CITED AUTHORITIES

Page

CASES

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

lectures explored how cancer might be induced by DNA

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 questiomntiti

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

not escaped our notice that the specific pairing we have

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.

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

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

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.

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).

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

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

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,

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

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*

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

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

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,

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