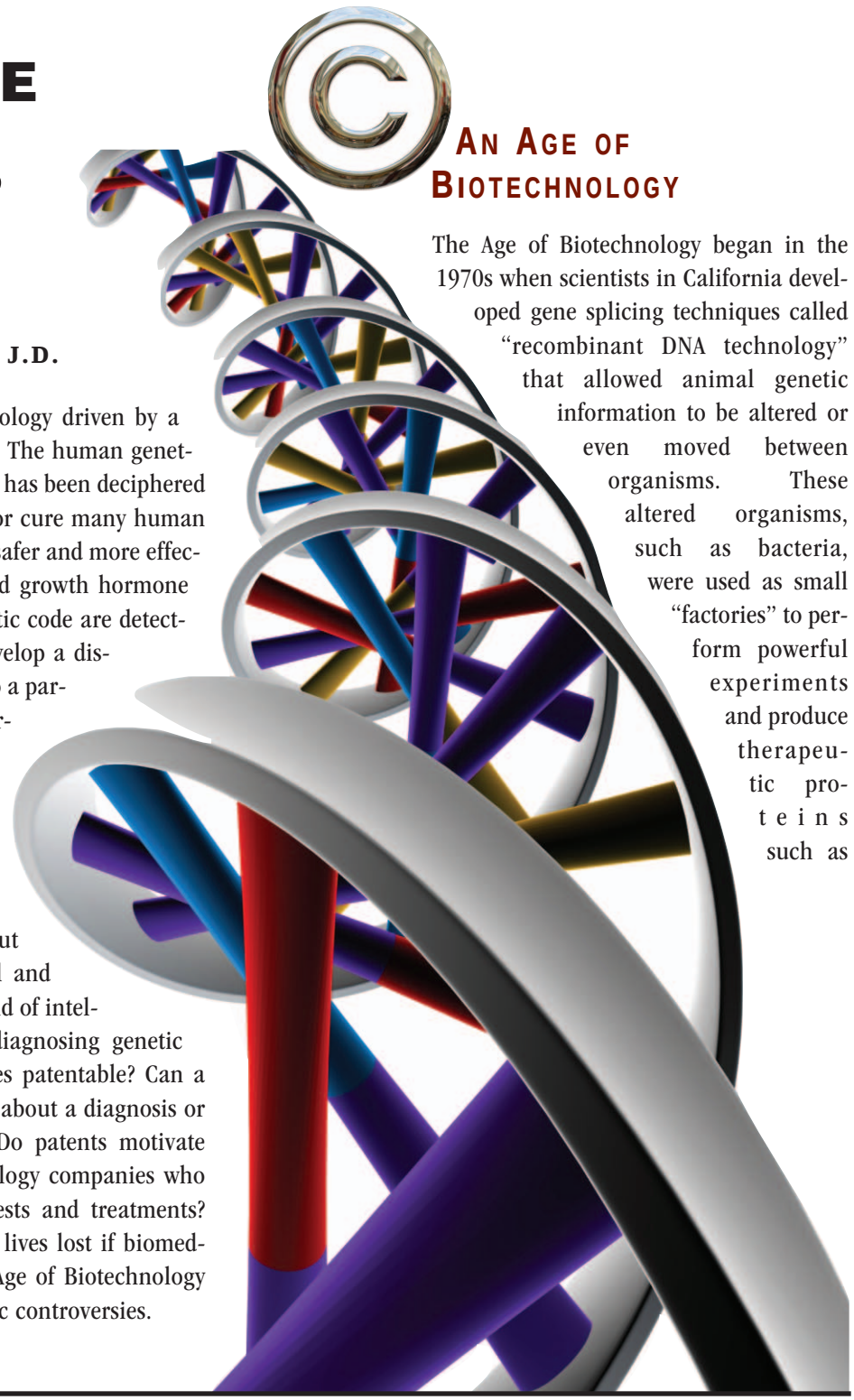
Patenting Biomedicine Inventions



BY WILLIAM D. NOONAN, M.D., J.D.

We live in an Age of Biotechnology driven by a revolution in genetic science. The human genetic code (the Human Genome) has been deciphered and even modified to help understand or cure many human diseases. Genetic engineering produces safer and more effective synthetic drugs such as insulin and growth hormone than in the past. Mutations in the genetic code are detected to predict whether a patient will develop a disease such as breast cancer, or respond to a particular drug. Physicians can even determine and analyze the entire genetic code of a patient to guide individualized treatment (personalized medicine) through a patient's lifetime.

Changes in biomedical technology have truly revolutionized medicine, but these advances have also created legal and ethical dilemmas, particularly in the field of intellectual property. Should methods of diagnosing genetic disease be patented? Are DNA molecules patentable? Can a physician infringe a patent by thinking about a diagnosis or taking steps to save a patient's life? Do patents motivate inventors or unjustly reward biotechnology companies who charge too much for their patented tests and treatments? Would medical progress be slowed and lives lost if biomedical patent rights were impaired? The Age of Biotechnology has been an era of ethical and economic controversies.

An Age of Biotechnology

The Age of Biotechnology began in the 1970s when scientists in California developed gene splicing techniques called "recombinant DNA technology" that allowed animal genetic information to be altered or even moved between organisms. These altered organisms, such as bacteria, were used as small "factories" to perform powerful experiments and produce therapeutic proteins such as

insulin. The United States Patent and Trademark Office (Patent Office) supported the growth of the early biotechnology industry by recognizing the patentability of these inventions and granting broad patent protection for them. The patents gave patent owners the right to exclude others from using their patented invention for a limited period (17 years at that time). The patent system had previously fostered the growth of many other industries throughout American history, and it was poised to do the same for biotechnology.

However the business community remained skeptical about the worth of biotechnology inventions until the United States Supreme Court in 1980 decided *Diamond v. Chakrabarty*. In that case the Supreme Court determined that genetically modified microorganisms were entitled to patent protection. The Court broadly encouraged patent protection for biomedical inventions by noting that "anything under the sun that is made by the hand of man" could be patented. Once it became clear that the courts would protect this remarkable new type of invention, a biomedical gold rush began. New biotechnology companies were formed and biomedical innovation began to revolutionize the diagnosis and treatment of disease. The United States had taken an early lead in protecting this new class of inventions and it soon became the world leader in this technology.

Also in 1980 Congress passed the Bayh-Dole Act to make it easier for universities to own patented inventions developed by their researchers using federal grant funds. The number of university patents increased greatly in subsequent years, and many of them were biomedical patents. Critics argued that it was wrong for government-sponsored research to be patented since it had been paid for by the public and should be free for all to use. However, the critics were silenced by the success of the Bayh-Dole Act in encouraging the transfer of patent rights to biotechnology companies to further develop the inventions, obtain FDA approval where needed, and sell the inventions commercially. In the absence of patent protection too many government-financed innovations had been unable to make the expensive transition from the laboratory to the marketplace. With patent protection the inventions became the foundation of successful new biotechnology companies that spurred the American economy and revolutionized industries from agriculture to medicine.

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The Human Genome

The 1990s brought a new era of DNA research as scientists started to decode the human genetic blueprint that is known as the "human genome." The federal government financed a $ 3 billion project to decipher the genetic code (DNA sequences) and massive amounts of valuable information began to emerge about the structure of human genes, mutations that cause

disease, and possible cures. Patent applications were soon filed on thousands of DNA sequences derived from human genes and a new controversy emerged about whether "human genes" were patentable. The United States Patent Office decided that human genes as they occur in the human body are not patentable, but DNA molecules that encode the genes could be patented only if they were in an isolated or purified form as they were found in the laboratory and not in a human body. The transformation of the underlying genetic information into a useful laboratory invention made it patent eligible.

Patenting Medical and Surgical Procedures

The success of these biotechnology patents encouraged physicians to patent methods of medical and surgical treatment. For example, an eye surgeon patented a method of cataract surgery that used a curved self-sealing incision. Many medical organizations complained that such "medical procedure" patents would limit the ability of physicians to choose the best treatment for a patient, or even expose the doctor or others to patent infringement damages for performing a patented procedure in an emergency without first obtaining a patent license. For example, if the Heimlich maneuver had been patented would it prevent a bystander from saving a choking person? Congress intervened in 1996 to generally shield individual physicians from monetary damages, but allowed medical procedure patents to be enforced against companies that made medical devices and drugs.

Supreme Court Intervenes

The last 15 years have been a time of diminishing patent rights for biotechnology inventions. Courts have applied an increasingly stringent test of patentability that has made it more difficult to patent inventions in the life sciences. A recent example is the patent in *Mayo v. Prometheus* in which the correct dosage of a thiopurine drug was established by administering the drug to a patient, measuring the level of the drug metabolites in the blood, and determining whether the dosage of the drug should be adjusted based on the test result. Last year the United States Supreme Court found the patent invalid because it impermissibly patented

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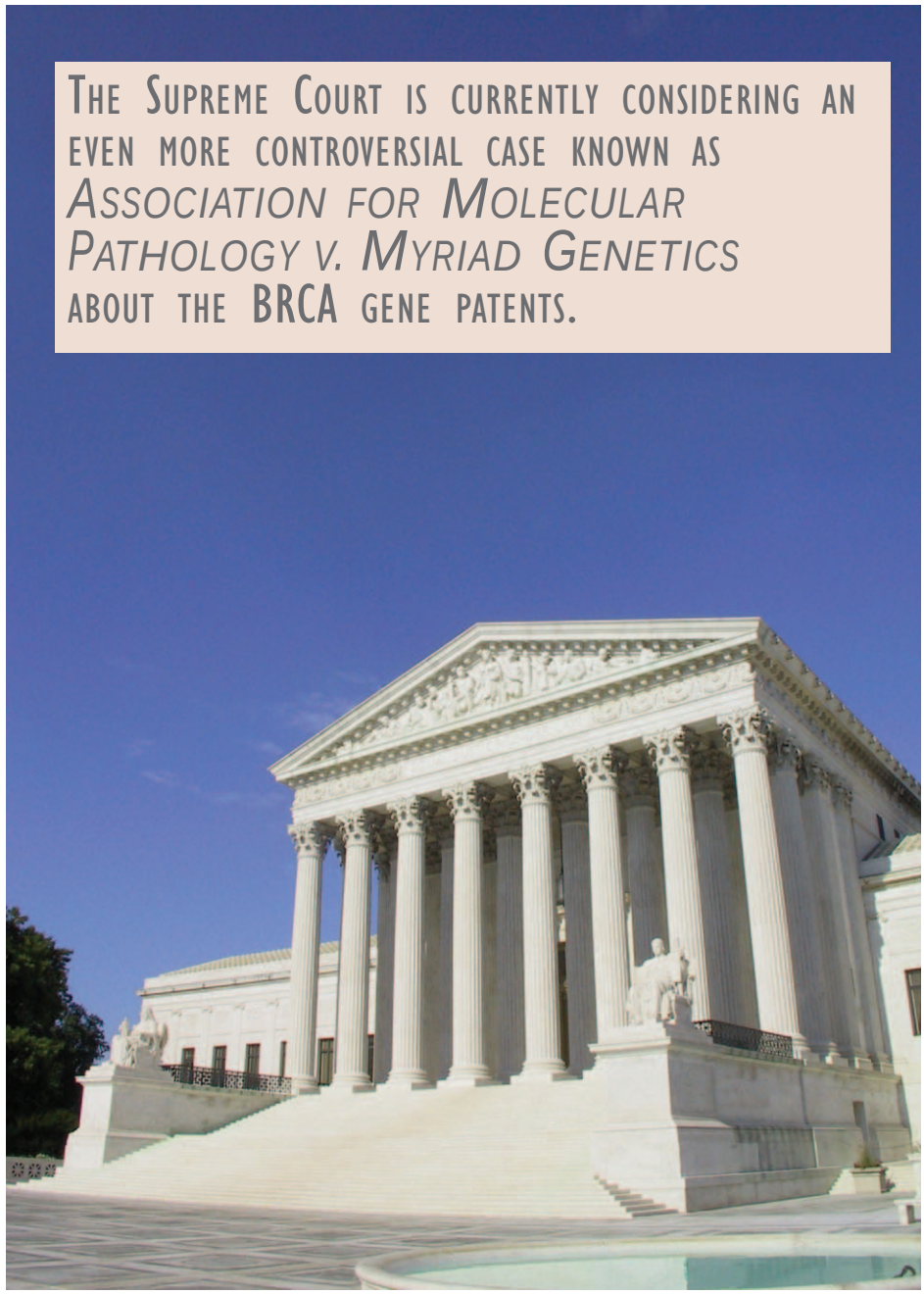

a natural law and would have interfered with a physician's treatment decisions. This decision has grave implications for the patentability of many methods of medical diagnosis and treatment.

The Supreme Court is currently considering an even more controversial case known as *Association for Molecular Pathology v. Myriad Genetics* about the BRCA gene patents. This long-running controversy began in the 1990s when scientists at the University of Utah and elsewhere discovered two genes (known as BRCA1 and BRCA2) that were mutated in women who developed breast cancer. Identifying the genes and the cancer-causing mutations gave physicians a powerful new tool to predict whether a woman was likely to develop breast cancer. Women with the mutation could be monitored more closely to find early-stage tumors. Some women with the mutation even decided to have their breasts removed to prevent the disease from developing.

Rights of Patients and Users

The BRCA inventions were licensed to a biotechnology company called Myriad Genetics which eventually obtained patents on "isolated" forms of DNA sequences that could be made only in a laboratory and were not found in the same form in the human body. The company also patented methods of predicting whether a woman would develop breast cancer by determining whether a woman carried the mutated gene. Since Myriad Genetics held the patents they were able to exclude other companies and even universities from performing the test in competition with them. As the sole source of the test Myriad Genetics was able to charge $2,000 — $3,000 for each patient who was tested.

Myriad's competitors complained that they were unable to perform the profitable patented test, and uninsured patients were often unable or unwilling to pay for it. Some bioethicists argued that it was unethical for any company to have patent rights on an invention that was derived from our common genetic heritage. The American Civil Liberties Union filed a suit on behalf of the patent's opponents. A decision from the Supreme Court is expected this summer and many observers think the Court will decide that isolated DNA sequences cannot be patented because they are too similar to molecules found in nature. If that were the outcome, then the United States would be the only country among the major industrialized nations of the world to take that position. Although genetic tests and other biotechnology products would probably be less expensive without patent protection, the risk is that they will be developed in other countries or not at all.

The Supreme Court is also currently considering another case related to seeds patented by Monsanto. The issue is whether a farmer can infringe Monsanto's patents by harvesting the patented seeds from plants and using them to grow a new crop. The ability of this patented invention to "replicate itself" by natural growth outside a laboratory has stirred controversy about the types of acts required to commit patent infringement.

William D. Noonan, M.D., J.D. is a partner at Klarquist Sparkman, LLP in Portland, Oregon. He has degrees in both law and medicine (JD/MD) and specializes in biomedical patent law.

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