INTRODUCTION

Who, if anyone, should own the information contained in your genes? Humans have thousands of genes contained in 23 pairs of chromosomes. These genes create the blueprint for our biology and determine who we are, what we look like, and, in some cases, what diseases we will get. There is a lot at stake, both medically and financially, in deciding who owns this knowledge.

The burgeoning understanding of the genetic code has spawned the field of genomics, which holds the prospect of tailoring medical care to each person’s individual makeup. This new area of medicine has the potential to save countless lives. It has already led to clinical tests to assess the risk of various serious diseases, including several forms of cancer.

The success of genomics is a result of the combined efforts of university research, which has generated many of the basic discoveries, and private corporations, which have developed commercial applications. It is, in effect, a team effort that has produced breakthroughs in many areas of medicine. The tests that are available to clinicians today have flowed from the contributions of both efforts.

Whereas academia and industry form the partnership that moves genetic medicine forward, their modes of operation differ quite a bit. In one important way, this difference has dramatic legal implications—the protection granted to the intellectual property that underpins their efforts, in other words, ownership rights to the genetic information involved. Academia relies on the wide dissemination of knowledge; private industry relies, to a greater extent, on the exclusive use of knowledge.

Most companies that commercialize genetic technologies seek patent protection for the information on which they rely. This means that for a period of 20 years, they effectively own it. Many academic researchers, as well as some clinicians, claim that this exclusive use inhibits their ability to further advance knowledge or to fully translate discoveries into benefits for patients. These conflicting goals have created a considerable legal controversy that remains unresolved. A lawsuit filed in May by a group of plaintiffs led by the American Civil Liberties Union (ACLU) seeks to produce greater clarity by restricting gene patent rights.

THE NATURE OF GENE PATENTS

The Supreme Court first recognized the patentability of genetic technologies in 1980. Since then, the U.S. Patent and Trademark Office (PTO) has granted tens of thousands of such patents, many covering human genes. These include the information contained in 20% of the human genome. Some of those patents have yet to find commercial applications, but many form the basis for important medical technologies, including diagnostic tests.

At the same time, critics ask how a private individual or corporation can own patent rights to part of the natural makeup of human beings. Human genes are hardly an “invention”; they are part of nature. Based on what rationale can a private entity hold exclusive rights to their use?

Under the law, a discovery or invention must exhibit several elements to merit patent protection. It must be useful, non-obvious, and novel. It must also represent a specific design or process rather than an abstract concept, a general idea, or an item readily found in nature. Even though genes by themselves do not meet these criteria, specific processes for isolating genes that have practical applications have been found to satisfy them. This is the way the PTO has interpreted the legal status of gene patents, and it has issued patents accordingly.

Despite the PTO’s position on the subject, the matter remains far from settled. There have been few court decisions to provide guidance. Some analysts argue that genes should no more be subject to patents than specific parts of the human anatomy. Opponents counter that the identification of individual genes represents original discoveries that deserve legal protection. This protection is seen as a necessary incentive to reward innovators for their expense and effort.

THE ACLU’s LAWSUIT

The recent lawsuit challenges a set of patents held by Myriad Genetics of Salt Lake City, Utah. The patents protect information concerning two genes linked to breast and ovarian cancer, BRCA1 and BRCA2. The case arose from the experience of Genae Girard, a 39-year-old resident of Austin, Texas, who took a test devised by Myriad to assess her risk for ovarian cancer. When the test came back positive, she sought a second opinion, but she was prevented from receiving one because the patents blocked anyone else from analyzing the same genetic sequences.

Besides the ACLU and Ms. Girard, several other individuals and organizations have joined as plaintiffs. These include the American College of Medical Genetics, the College of American Pathologists, and the Boston Women’s Health Book Collective. In addition to Myriad, the PTO and the University of Utah Research Foundation, which has an interest in the patents, were named as defendants.

Should Your Genes Be Subject To Patents?

No, Says a New ACLU Lawsuit

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The suit, which was filed in federal court in New York, seeks to have Myriad's patents declared invalid. It claims that they are so broad that they effectively bar scientists from doing any meaningful work with the genes involved and that this violates the First Amendment to the Constitution. The suit also seeks to have all human gene patents declared invalid, because genes are products of nature.

Supporters of gene patents claim that this form of legal protection is essential to promote innovation, but the ACLU contends that it is having the opposite effect. Exclusive rights to genetic knowledge block others from conducting research on the same genes, and academic research depends on unimpeded access to information. Exclusive rights to genetic knowledge also create monopolies that impede market forces while they are in effect.4

THE STATUS OF GENE PATENTS

Although the PTO has issued many gene patents, few of them are held by private companies that would have an interest in locking up the knowledge involved. The two entities with the largest number of patents are the University of California and the U.S. government.5 Among others holding large numbers of patents are several other universities. Going forward, the impact of such patents may start to recede. The number issued has leveled off and has even started to show a slight decline in recent years.5 Moreover, with patents lasting 20 years, those issued in the late 1990s will begin to expire over the next decade or so.

At the same time, technology may be overtaking some gene patents. It is becoming cheaper and easier for individuals to sequence their own DNA, as DNA co-discoverer James Watson has done. This may permit an end run around some patents.

There are, in fact, few instances in which gene patent holders have actually sought to prevent academic researchers from conducting investigations. In most instances, it is not worth the expense of litigation to do so. In 2006, a committee of the National Research Council concluded that access to patents rarely imposes a significant burden on academic biomedical research.5 A task force of the federal Department of Health and Human Services issued a draft report in March 2009 that found little evidence of widespread overpricing of patented genetic tests or of limited patient access.6 However, the group also concluded that patents provide only a minor stimulus for private genetic innovation.

Nevertheless, in at least a few instances, gene patents appear to have stifled research and patient access to genetic tests. For example, Myriad has issued a cease-and-desist order against a group of Yale University scientists who are studying its patented cancer genes.7 Moreover, despite the infrequency of patent enforcement, the presence of patent rights presents a potential liability risk to scientists conducting investigations and to the institutions in which they work, which may have a chilling effect on their activities.

Patients have faced restrictions on access to genetic tests in some situations, as did Ms. Girard when she sought to obtain a second analysis of her ovarian cancer risk. Even for an initial test, financial barriers may arise. Myriad has reimbursement contracts with many, but not all, health insurers to cover the cost of its tests. Patients with the wrong kind of insurance have to pay thousands of out-of-pocket dollars to receive them.

THE FUTURE OF GENE PATENTS

Depending on technological and legal developments, the status of genetic patents will almost certainly face significant changes. As knowledge about the human genome becomes more sophisticated, researchers will probably discover more uses for individual genes. This work will encourage more patent applications, but it may also lead to a greater range of alternatives to patented technologies.

At the same time, the legal status of human gene patents will face closer scrutiny in the courts. The ACLU lawsuit will most likely lead all the way to the Supreme Court, which has yet to definitively rule on the issue. When it does, the question of whether genetic technologies represent patentable scientific inventions or phenomena of nature, freely available to everyone, may finally be resolved. This clarity could go a long way toward creating a legal environment in which the potential of genomic medicine can be fully realized.

REFERENCES