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Editorial

Patenting Human Genes: The Myriad Controversy

The controversy over human gene patents was reignited in March 2010 when a US Federal District Court decided that isolated human gene sequences are not patentable.¹ An appeal is pending, although the US Department of Justice filed a friend-of-the-court brief in the case in late October, arguing that such gene sequences should not be patentable.² Because this case may eventually find its way to the US Supreme Court, the ruling could have significant implications for gene-based medical therapies and for the biotechnology industry overall. It is therefore important to assess both the past and present context of this controversy, taking into account scientific research, health care access, and ethical concerns.

Patents are government grants that give their owners the right to exclude anyone else from making, using, or selling the inventions they describe.³ To be eligible for a patent, the invention must be new, useful, and not obvious to someone working in the same field as the inventor.⁴ Laws of nature, physical phenomena, and abstract ideas are not patentable, but, according to the US Supreme Court, “anything under the sun that is made by man” is potentially patentable.⁵ For example, a microorganism as it exists in nature is not patentable, but a version of that microorganism that has been genetically modified by man is. The US Patent and Trademark Office (USPTO) relies on this reasoning when issuing patents on isolated human gene sequences, because human intervention is required to extract and purify them.⁶ The European Union takes a similarly open stance toward gene patents and has issued a directive permitting isolated human gene sequences to be patented.⁷ Not surprisingly, gene patents have flourished. It is estimated that nearly 20% of human genes are associated with at least one US patent and that the number of DNA-related patents exceeds 40,000.⁸

The current controversy over gene patents involves Myriad Genetics, Inc., a biotechnology company that owns patents on isolated forms of 2 human genes, *BRCA1* and *BRCA2*, which have been linked to hereditary breast and ovarian cancer. As the owner of the patent, Myriad can prevent others from using *BRCA1* and *BRCA2* in research, diagnostic, and therapeutic applications. Myriad also has the ability to charge high prices to companies wishing to use these genes. Thus, the American Civil Liberties Union and the Public Patent Foundation filed a lawsuit claiming that Myriad’s patents were invalid, stifled biomedical research and diagnostic testing, and limited patients’ access to medical care. The court agreed with the plaintiffs and found that isolated gene sequences are not patentable because they are not “markedly different” from the gene sequences as they exist in nature.¹ This was a surprising result, given that the matter of the patentability of isolated human gene sequences in the United States had been considered settled. While this case could be dismissed as an aberration, certain to be overturned or curtailed on appeal, other judges also have questioned the patentability of isolated gene sequences.⁹ As noted, the US Department of Justice has taken the position that such sequences should not be patentable.² Accordingly, there is a real possibility that US courts will bar the patenting of human genes. Such a decision would place the United States in opposition to the European Union, and because the USPTO and its European counterpart, the European Patent Office (EPO), are among the largest patent offices in the world,¹⁰ the resulting discordance could have profound implications for international policy.

Although the Myriad case is concerned with genetic diagnostic testing, the District Court ruling calls into question the validity of numerous patents that have been issued for other gene-based inventions, including gene-based biologic therapeutics. Many existing patented biologic drugs are biotech blockbusters, such as human insulin and insulin analogues, the rheumatoid arthritis drug etanercept, and the anemia drug erythropoietin. While the patents for such blockbuster agents generally cover more than the isolated and purified gene sequences on which they are based, the uncertainty over the scope of patent protection for biologic drugs could deter potential investment, regarding the development of new gene-based therapies and adversely affecting the biotechnology industry.

Given the impact of a potential ban on gene patenting, we need to further consider the arguments for and against such patents. Some opponents claim that human gene patents hinder scientific research, because investigators hop-

ing to work with patented genes need to seek permission from the patent owners, thereby increasing costs and inefficiencies. These costs, they suggest, may become so prohibitive that researchers will stop working with patented genes altogether. However, these claims have not yet been substantiated. In fact, there is little evidence that gene patents are actually having a deterrent effect on biotechnology research,^{11,12} suggesting that various stakeholders may be using licensing agreements or other workarounds to facilitate research.

From the standpoint of health care access, some critics of gene patenting argue that if a particular patented gene therapy or diagnostic test is deemed medically necessary, a patient will have little choice but to obtain the treatment or test from the patent owner or the owner's licensee. Indeed, there is evidence that patenting of diagnostic tests does restrict patients' options.⁸ Although such restrictions could increase patient burden and costs, this effect is not unique to human gene patents; any patents granted to health care products can have such effects. Thus, the high cost of patented therapies is a drawback of the patent system as a whole and is not specific to gene patents. After all, our patent system is based on the premise that patent exclusivity is needed to incentivize invention and innovation. Pharmaceutical companies have long contended that patent and market exclusivity allows them to recoup the costs of drug development and finance new research.¹³ While gene patents may play a crucial role in promoting biotechnology innovation, there is insufficient evidence to determine whether the patent system is the optimal way of encouraging such innovation.

Furthermore, some posit that the human genome is qualitatively different from other naturally occurring entities and is even distinct from the DNA of plants and other animals. Therefore, the argument goes, human dignity should preclude anyone from owning patents on human genes.¹⁴ Moreover, if the human genome is part of man's common heritage and if individuals have an inalienable right to ownership of their bodies, including their genes, what right does any single individual have to own part of the genome?^{15,16} The difficulty with these arguments is that the patent owner merely owns the isolated gene and does not control the genetic information encoded by that gene. In fact, these moral objections were made with respect to Myriad's gene patents in opposition proceedings before the EPO, although they were ultimately rejected.^{17,18} Perhaps the underlying thrust of these arguments is that by allowing patent owners to control isolated gene sequences, we may unwittingly be enabling them to control the encoded genetic information common to us all.

A final decision in the Myriad case may be a few years off, depending on whether the US Supreme Court decides to weigh in. But are we, as a society, prepared for this decision when important questions remain unanswered? For example, more evidence is needed to determine whether gene patents actually impede the development, commercialization, and/or utilization of important therapies and diagnostic tools. We need to critically consider whether controlling an isolated gene sequence translates into de facto control of the genetic information encoded by that sequence. How different is an isolated gene sequence from the gene sequence as it resides in the human body? The scientific community has a responsibility to enrich the debate on this controversial topic by providing empirically based, thoroughly deliberated answers to these and other questions. The answers will ultimately help inform the important decision society must make regarding the propriety of patenting human genes.

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