12-17-2010

The Pros and Cons of Gene Patents

Chester S. Chuang
Golden Gate University School of Law, cchuang@ggu.edu

Denys T. Lau
University of Illinois at Chicago, College of Pharmacy

THE RECORDER
ESSENTIAL CALIFORNIA LEGAL CONTENT

The Pros and Cons of Gene Patents

Chester S. Chuang and Denys T. Lau
2010-12-17 11:40:42 AM

The debate over human gene patents was recently reignited by New York federal Judge Robert Sweet, when he found isolated human gene sequences unpatentable in Association for Molecular Pathology v. U.S. Patent and Trademark Office , 702 F.Supp.2d 181 (S.D.N.Y. 2010). An appeal of the decision is pending, and in October, the U.S. Department of Justice filed an *amicus curiae* brief in the case arguing that such gene sequences should not be patentable, contradicting long-standing practices of the United States Patent and Trademark Office.

Given the potent impact of a possible gene patent ban on gene-based medical therapies and the biotechnology industry at large, the arguments for and against patenting human genes must be carefully considered. Unfortunately, much of the current legal debate has centered on technical aspects of patent law doctrine and not the significant policy arguments that also need to be resolved. It is therefore important to evaluate the issue in a fuller context, taking into account health care access, scientific research and ethical concerns.

Patents give their owners the right to exclude anyone else from making, using or selling the inventions they describe. To be eligible for a patent, the invention must be new, useful and non-obvious to someone in the same field as the inventor. Laws of nature, physical phenomena and abstract ideas are not patentable, but as the Supreme Court stated in *Diamond v. Chakrabarty* , 447 U.S. 303 (1980), "anything under the sun that is made by man" is potentially eligible. For example, a microorganism as it exists in nature is not patentable, but a modified version of that microorganism that has been genetically altered by humans is. Accordingly, both the USPTO and its European counterpart, the European Patent Office (EPO), consider isolated human gene sequences patentable because human intervention is required to extract and purify them. It is estimated that about 20 percent of human genes are associated with at least one U.S. patent and that the number of DNA-related patents exceeds 40,000.

Because the patentability of human genes in the U.S. was thought to be a settled issue, Judge Sweet's ruling last March was surprising. Myriad Genetics, a biotechnology company, owns patents on isolated forms of two human genes, BRCA1 and BRCA2, which have been linked to hereditary breast and ovarian cancers. As the patents' owner, Myriad can prevent others from using BRCA1 and BRCA2 in research, diagnostic or therapeutic applications. This exclusive right also gives Myriad the ability to charge high prices to companies that wish to use the genes. The American Civil Liberties Union and the Public Patent Foundation filed a lawsuit claiming that Myriad's patents were invalid. They alleged that these patents

stifled diagnostic testing and biomedical research and limited patients' access to medical care. Sweet ruled in favor of the plaintiffs and found that isolated gene sequences were not patentable because they were not "markedly different" from the gene sequence as it exists in nature. While this case could be dismissed as an aberration certain to be overturned or curtailed on appeal, some appellate court judges have subsequently questioned the patentability of isolated gene sequences. As noted earlier, the DOJ has aligned its position with Sweet, arguing that such sequences should not be patentable. Accordingly, there is a real possibility that U.S. courts will bar the patenting of human genes, consequently putting U.S. gene patent policy in opposition to that of the EU. Because the USPTO and the EPO are among the largest patent offices in the world, the resulting discordance could have profound international policy implications.

Some critics of gene patenting argue from the health care perspective that if a particular patented gene therapy or diagnostic test were deemed medically necessary, patients would have little choice but to obtain those treatments or testing products from the patent owner or the patent owner's licensee. Indeed, there is evidence that patented diagnostic tests restrict patients' options with respect to those tests. While such restrictions could increase patient burden and costs, this is not unique to human gene patents. Any patents granted to health care products can cause such deleterious effects and criticizing the high cost of patented therapies is a critique of the patent system as a whole and not specifically of 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 cost of drug development and finance new research. Indeed, even though the *Myriad* case is concerned with genetic diagnostic testing, its ruling calls into question the validity of numerous issued patents related to other gene-based inventions, including gene-based biologic therapeutics. Many existing patented biologic drugs are big-selling biotech blockbusters, such as human insulin, the rheumatoid arthritis drug etanercept, and the anemia drug erythropoietin.

While the patents covering such blockbusters generally claim more than just the isolated and purified gene sequences upon which they are based, the uncertainty over the scope of patent protection for biologic drugs may deter potential investment, retarding the development of new gene-based therapies and adversely affecting the biotechnology industry. However, while gene patents may play a crucial role in promoting biotechnological innovation, it is important to acknowledge that there remains insufficient evidence to conclude whether the patent system is the optimal way to encourage such innovation.

From a research standpoint, some opponents of gene patenting claim that human gene patents may hinder scientific progress because investigators hoping to work with patented genes need to seek out the various patent owners for their permission, thereby increasing costs and inefficiencies. These costs may become so prohibitive that researchers would stop working with patented genes altogether. However, these claims have not been substantiated to date. In fact, there is little evidence that gene patents are actually having a deterrent effect on biotechnology research. This suggests that licensing agreements or work-arounds may occur among different stakeholders that facilitate gene-based research.

Ethical and moral arguments against human gene patents are based on the premise that the human genome is qualitatively different from other naturally occurring things, and even distinct from the DNA of other plants and animals. Therefore, human dignity should prevent anyone from owning patents over human genes. After all, if the human genome is part of human's common heritage, and if each person has an inalienable right to ownership of one's body, including one's genes, what right does any one person have to own part of the genome? The difficulty with sustaining these arguments is that the patent owner merely owns the isolated gene extracted from its natural state and does not control the genetic information encoded by that gene.

Relying on this line of reasoning, some legal experts dismiss these ethical and moral objections as contrary to existing patent law doctrine. But by narrowly focusing on patent law doctrine are we missing the point? The fundamental issue may not be whether isolated human gene sequences are patentable (i.e., whether isolating and purifying human gene sequences requires enough human intervention to make them patentable), but whether isolated human gene sequences should be patentable. By permitting patent owners to control isolated gene sequences, are we inadvertently enabling them to control the encoded genetic information that is common to us all?

If the U.S. Supreme Court decides to weigh in, a final decision in the *Myriad* case could be a few years away. However, as a society are we ready for the ruling when important questions remain unanswered? For example, more evidence is still needed to determine whether gene patents actually facilitate or hinder the development, commercialization, and/or utilization of important gene-based 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 thereby. The legal community has the responsibility to work with biomedical and health services professionals to enrich this debate by collectively providing well-deliberated and empirically based answers to these and other important questions concerning the propriety of patenting human genes.

Chester S. Chuang is an associate professor of law at Golden Gate University School of Law, and Denys T. Lau is an associate professor at the University of Illinois at Chicago, College of Pharmacy.

In Practice articles inform readers on developments in substantive law, practice issues or law firm management. Contact Vitaly Gashpar with submissions or questions at vgashpar@alm.com.