"Who Owns Your Genes?" Event Illuminates Arguments For and Against DNA Patenting

Shawna Williams

Patenting human genes is a "massive social experiment," Robert Cook-Deegan declared early in a July 10 seminar on DNA patenting. The diversity of views at that event indicate there's no consensus on how that experiment will turn out—or on whether it should be conducted at all.

The seminar, "Who Owns Your Genes? Intellectual Property and the Human Genome," was part of the Genetics and Public Policy Center's Genetics Perspectives on Policy Seminars (GenePOPS) series, and was co-sponsored by the Center for Genome Ethics, Law & Policy at Duke University's Institute for Genome Sciences & Policy. GenePOPS explore issues raised by human genetic technologies and foster discussion about their impact. Despite a thunderstorm that rattled the room and drenched many audience members en route, "Who Owns Your Genes?" drew an audience of around 100 people to the National Press Club, representing law firms, academia, advocacy groups, the press, and government agencies.

Center Director Kathy Hudson began the program by welcoming attendees and introducing each of the four panelists: Cook-Deegan, the director of the Center for Genome Ethics, Law & Policy at Duke University's Institute for Genome Sciences & Policy; F. Scott Kieff, professor of law at Washington University, St. Louis, and fellow at Stanford University's Hoover Institute; Barbara Caulfield, executive vice president and general counsel for Affymetrix, Inc.; and Steve Haro, senior advisor and communications director in the Office of U.S. Representative Xavier Becerra.

I. The basics

Cook-Deegan laid the groundwork for the discussion, reminding the audience that to be patentable, an invention must be novel, useful, and nonobvious. Governments require that applicants for patents disclose their discoveries, he said, in exchange for legal protection from would-be copycats.

There are around 16,000 "sequenced-based" patents worldwide, Cook-Deegan noted, most of them based in the United States. These are patents involving a specific purified segment of DNA or its cousin, RNA. Of these, about 3000 are patents on human genes. The number of DNA-based patents rose sharply in the mid-1990s in the U.S., and this country is now far ahead of Japan and Europe in number of sequence-based patents granted, Cook-Deegan explained. But because of the "20-year litigation cycle" for patent law, the results of this "natural experiment" will only become clear in the next decade, he predicted.

Comparing the number of literature citations for three "seminal technologies" commonly used in molecular biology laboratories—one patented, two unpatented—Cook-Deegan said, "The thing to notice here is you can't really tell the difference too much in the adoption of these technologies. So if your theory is, 'if something's patented, nobody gets to use it'—wrong." Companies can and have patented and licensed genes in ways that limited patient access to tests, however: Cook-Deegan contrasted four such "infamous" cases with "success stories" such as erythropoietin, insulin, clotting factors, and immune modulators. The credit for the successes—in which profits are made while access to the therapies increases—lies with "very sophisticated" licensing agreements that ultimately benefit both consumers and patent holders, he said. Examples of patent functions in this field are to reward inventing institutions with a funding

stream, to induce investment in development of technologies, and to enable companies to carry out expensive safety and efficacy trials without fear that another company will cash in on their efforts, Cook-Deegan said.

He also described a study of the tone of four countries' press coverage of the Myriad company gene patenting controversy. (Myriad holds patents on two genes correlated with breast cancer, BRCA1 and BRCA2, and has not authorized other laboratories to test for those genes.) The tone of the coverage had been overwhelmingly negative, he noted, though with more neutral and positive treatment of Myriad in the United States than in other countries. The press is "probably driving the policy apparatus much more than the practices of the patent office and the practices of the businesses," he concluded.

II. "Gene patents are great"

"I understand that my job here is to be a bit of a trouble-maker," Kieff said, and he wasted no time in cutting to the chase, saying, "Biotech patents—gene patents—I think are great. And I think they're great not just for everybody—I think they're especially great for the little guys."

Kieff explained that his views are rooted in the field of New Institutional Economics, which focuses on the impact of laws, rules, and informal norms on economic development, rather than on more tangible factors such as capital, technology, and labor.

Kieff said the reason the United States is so rich is that our country has property rights in intangibles. "Modern economic growth is about intangible assets: it's about intellectual property, it's about contracts, and it's about finance or capital," he said. He used the example of the banking sector to show why property rights matter: Countries with strong property protections have much more robust banking sectors than countries without such protections, he said, which in turn benefits people who need to borrow money. Similarly, intellectual property (IP) rights in this country have led to an economy in which IP-based companies thrive, constituting the largest sector of the economy, he said. He said the United States began allowing patents on basic biotechnology in 1980, and that the biotech industry only took off at that point. Europe and Japan still don't patent basic biotech, he said, and so have been left behind in this sector.

Contrasting informal "norm communities" like open source software with legal IP protection, Kieff conceded "there are a lot of benefits" to norm communities, such as lower enforcement and administration costs. However, "it's very hard to merge and divide and bundle and trade the assets that lead to norm communities, and it's very easy to do that with property rights," he said, noting that the benefits of norm communities also tend to be confined to a homogenous group of insiders.

Moving to the specific case of gene patents, Kieff clarified that genes as they occur in nature cannot be patented; only the isolated or purified versions of DNA sequences can be protected in this way. He addressed the "anticommons problem," the idea that, for example, development of diagnostics that test multiple DNA snippets will be hampered by having to obtain permission from hundreds of patent holders. Patent holders have a financial incentive to strike a deal with someone who wants to license their discovery, Kieff said, so having to obtain multiple permissions is not in fact prohibitive.

While many have argued that drug patents reduce access to life-saving drugs in African countries, Kieff maintained that the real roots of Africa's health care problems—such as lack of mosquito control or effective drug distribution—are far more basic. In fact, stronger IP protections in poorer countries would enable people in

those countries to profit from their own intellectual capital, he said.

III. Natural phenomena vs. inventions

"There ought to be a balance between laws of nature, or natural phenomena, and inventions that people make. It's just that simple," Caulfield began. "It's not about the economics, it's about whether somebody really invents or discovers something."

An example of a natural phenomena that cannot be patented is purified iron, she said; another is the equation E=mc2. Similarly, purified DNA sequences such as the BRCA1 breast cancer gene should not have been patentable under the law, she said, although companies should be able to patent tests they develop for genes. "Let's put the ownership where the innovation is really going to occur, which is at the test, which is at the drug, which is at… if you've reinvented the DNA or changed its biochemistry, and reinserted it into a person, you can own that. But to own the basic piece, the basic DNA, is not right—it violates first principles of constitutional law and patents," she said.

A practical effect of the BRCA1 patent, Caulfield said, is to keep patients from verifying their test results for the gene with a second company, since only one (Myriad) is allowed to test for BRCA1.

Opposing gene patents does not mean opposing all patenting, she said. Gene patenting's practical consequences can be seen in cases like that of BRCA1, in which a company restricts scientific and medical research, she said: "If you have all of this rubric around DNA patents in the U.S., then the really good research is going to be done in places where they have more open ability to innovate at the test level."

The finding that most diseases are predicted by many genes has made gene patenting even less practical, Caulfield said, because diagnostic tests will have to incorporate many DNA segments, each potentially controlled by a separate patent holder.

"I think the people that are missing in a lot of these discussions are the patients," she said in conclusion. "They want more tests; they don't want just one DNA-determinative test, because it's better if more companies do it, if more doctors read it, and more people criticize the test."

IV. There ought to be a law…

"Simply put, the practice of gene patenting is wrong, ill-conceived, and stunts scientific advancement," Haro said, explaining that for these reasons, Rep. Xavier Becerra recently introduced H.R. 977, the Genomic Research and Accessibility Act. The act would prohibit the patenting of genetic material, but would not rescind patents that have already been issued. "Given that Congress has defined the scope of protected status to be 20 years from the point that the patent application was filed, if we enact this bill into law quickly, we will reach balance in less than two decades: a patent-free genome that does not hinder scientific research, business enterprise, or human morality," he said.

Arguing that the fact that genes are patentable now is no reason to continue the practice, Haro said, "Congress has a constitutional right to proliferate and reward the advancement of innovation, but it also has the responsibility to intervene should that advancement be misdirected or incorrect." Human genes are products of nature, he said, and hence, "patenting the gene for breast cancer or any other gene is the analogous equivalent to patenting air, water, birds, or diamonds."

Haro urged audience members to ask their representative or senator to support Becerra's bill quickly, since, he said, one-fifth of the human genome is already patented. The bill will encourage innovation, he said, since "medical innovation and economic advancement will

occur if the study of genes is allowed to happen unabated."

V. Audience reaction

Hudson began the discussion, asking Caulfield whether the harms to research, innovation, and test quality in the case of BRCA1 and BRCA2 are due to the patents themselves, or to Myriad's choice not to license the patents to anyone else. Caulfield said that both the patents and the licensing are the problem, since patents give the holders a right to control who can use a DNA sequence. Haro said that Myriad's patent on BRCA1 and BRCA2 has created a monopoly on tests for predisposition to breast cancer, and that the tests cost $3,000 each as a result. Cook-Deegan said that "patents are not the whole story," and pointed out that "colon cancer testing also costs about $2,500; there is no dominant patent position on colon cancer testing. So inherently it is expensive to do these tests." Kieff said that only the isolated, purified versions of genes can be patented—not those that exist in the human body—and that there is a precedent for this, since "isolated strawberry flavoring, isolated adrenaline, isolated insulin—all of those things actually are patented, were patented, and led to very successful industries."

Jonathan Rockoff of the Baltimore Sun asked whether, beyond price, any specific harms had arisen from Myriad's monopoly on BRCA1 and BRCA2. Caulfield responded that it would be very difficult to prove statistically that patents have quelled research on the two genes, but asked "if there's only one test and it's done in one lab—and that's what gene ownership means you can do—then how do you ever double check what that lab is doing?" Kieff said that there have, in fact, been studies on the effect of patents, and that, "the data shows patents don't block research." Haro cited a National Science Foundation report that "said that gene patents at current were not hampering research, but they will."

Paul Billings of Lab Corp and the University of California said, "I don't think there's any evidence that [Myriad is] an any better or worse lab than many of the other ones who are providing clinical services in the United States." Kieff said that while patent suppression does happen, if the government mandates that patent holders license their technologies, those who want to license the technologies gain an unfair advantage in negotiations. But, he said, in general companies have an interest in gaining as many users of their product as possible, and will price their goods accordingly.

Kurt Calia of Covington & Burling LLP asked about patent pools for gene patents (in which companies assign patent rights to a collective that acts as a licensing body and grants non-exclusive licenses to the patents in the pool for a fee, part of which goes to the patent holder for the IP licensed and part of which goes to the collective for administrative costs). Haro said that gene patenting should be stopped immediately, but that it would be fine to pool existing gene patents. Caulfield said such a pool would be "a very good answer to a lot of these issues," providing it was run with the right rules. Kieff did not address gene patent pools, but used his closing remarks to say that the existence of airplanes, telephones, TVs, the Internet, and $1,000 laptop computers proves that patents on basic technologies don't prevent those technologies from being used, and that patents should be respected. Cook-Deegan said there are many good reasons to have patent pools for genes. He cautioned reporters in the audience that, "if you're covering stories where intellectual property is part of the story, it's not always going to be about money changing hands." Other political, social or medical considerations may also affect how a gene patent story plays out.

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Hopkins University by The Pew Charitable Trusts and by research funding from the National Institutes of Health. She earned her B.A. in Biochemistry at Colorado College and a graduate certificate in Science Writing at the University of California, Santa Cruz.

Letter to the Editor

I am writing in response to the article arguing for the ban of gender selection technology in connection with in vitro fertilization that was published in the last issue of the Biotech Briefing. The article raised several issues in my mind.

First, in the United States, a woman may determine the sex of her fetus using prenatal diagnosis (e.g., ultrasound, amniocentesis), and may choose to terminate pregnancy based on this information. This technology has been available for many years. And, also for many years, abortion has been available to women without restrictions such as the requirement to give a reason for the procedure. It is theoretically possible, therefore, that gender-based abortions could have been occurring in the U.S. for quite some time. Despite this possibility, I am not aware of any information indicating that selective abortion is in any way a common or routine occurrence, or that such practice has resulted in a gender imbalance in the U.S. population.

Second, 42% of clinics providing in vitro fertilization ("IVF") already allow gender selection without medical cause as part of preimplantation genetic diagnosis.[1] Despite the fairly widespread availability of this technology, again, I am not aware of any evidence indicating that it has resulted in more births of one gender than another.

While gender selection is certainly an issue in many countries (China, India, and Korea come to mind), there appears to be no strong preference for one gender over another in the United States, so prohibition of the procedure seems unwarranted. Even assuming, for the sake of argument, that gender selection in the U.S. results in the birth of more males than females, there is also the issue of whether possibly furthering societal discrimination against women ought to outweigh the personal choice of an infertile woman or couple from having a child of the gender for which she or they wish, particularly when it may be the only child she or they are able to have.

Further, regulating or prohibiting the use of gender selection via IVF would raise a number of issues, not the least of which is the issue of a woman's constitutional right to abortion. The law in the US is that a woman may have an abortion for any reason she chooses. It would be legally challenging to reconcile a prohibition on gender selection via IVF with the ability for women to terminate pregnancies for any reason, including the sex of the fetus.

This is not to say that I am opposed to national regulation of IVF clinics. Regulation may be beneficial, particularly if it could clarify the inconsistent state laws on disposal of excess IVF embryos, and bring an end to an ongoing moral wrong—the denial of access to treatment for women that do not meet the clinics' screening criteria because of sexual orientation or other nonmedical reasons.[2]

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Disclaimer: It is relevant to the content of this letter that Ms. Ince's practice includes the life sciences. It is also relevant that her mother used IFV due to infertility, which resulted in the birth of Ms. Ince's twin brothers. Ms. Ince does not believe that she has the right to disclose whether her parents used gender selection technology in conjunction with their IVF procedure.

[1] Survey is part of a report prepared by the Genetics and Public Policy Center,