New York's Community BioLab

Via Electronic Mail To genetest@uspto.gov and First-Class Mail

Saurabh Vishnubhakat
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United States Patent and Trademark Office
Customer Service Window, Mail Stop Comments - Patents
Randolph Building - 401 Dulany Street
Alexandria, VA 22314

Re: Docket. No. PTO-P-2012-0003

Dear Mr. Vishnubhakat:

Thank you for the opportunity to comment regarding the effects of patents and exclusive licenses on genetic diagnostic testing.

About Genspace

Genspace is a nonprofit community laboratory dedicated to promoting citizen science and access to biotechnology. Genspace members include artists, biologists, engineers, and university faculty. Since 2009, Genspace has served the greater New York area by providing subscription based access to a Biosafety Level One laboratory for educational programs in life sciences, laboratory safety, and for independent research. We also support science education in local schools and universities through outreach programs, mentorship, and by providing space and guidance for students competing in science competitions. Genspace has received praise for its educational efforts from *The New York Times*, *Science*, and in other media.

We ask that the Commissioner consider our comments in light of our experience fostering independent research and scientific education.

Human Rights To Individual Inquiry Must Be Held Paramount Over Genetic Patents

We believe that every individual has an inalienable right to research her own genotype regardless of any conflicting legal rights conferred by a patent. While some might characterize this right as the sort of common law "experimental use" that predates the Patent Act, we ask the Commissioner to consider whether it deserves to be recognized as more. An individual's interest in understanding her own genetic identity and investigating what makes her unique surpasses even a constitutional right to medical privacy.[1] It implicates the human dignity that is the source of all inalienable rights.[2]

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[1] *See e.g.*, *Roe v. Wade*, 410 U.S. 113, 152 (1973) ("[T]he Court has recognized that a right of personal privacy, or a guarantee of certain areas or zones of privacy, does exist under the Constitution.")

[2] *See* U.N. DECL. HUM. RIGHTS ART. 1.

The current debate over what genetic tests can be patented and who should be permitted to perform them assumes that individuals cannot perform the tests for themselves. A growing number of individuals can and will test their own genotypes. Some day soon, sequencing one's own DNA will become as much a part of school science curriculums as dissecting a frog. But today, it has been estimated that 100% percent of the human genome is already patented in some way. How is any student, independent researcher, or intellectually curious individual to know whether she will violate a patent by performing such a test on herself? In the face of a growing mass of genetic testing patents, how can we avoid a chilling effect?

Genspace believes that the right to independent research into one's own genotype must be recognized as paramount over any third-party patent right, and urges the Commissioner to make a clear statement that protects an individual's right to perform genetic tests on herself and to produce patented products for her own individual research.

Educators Need An Exemption To Protect From Secondary Liability

The potential effect of genetic testing patents on science education also raises tangible free speech concerns. Recent studies suggest that genetic patents are enforced more aggressively than patents in other sciences.[3] While the risk that a patent-holder might seek to enforce its rights against an individual who investigates her own genotype may seem fairly low, the potential secondary liability for a school or educator who teaches how to perform a patented process or how to produce patented synthetic DNA molecules (such as cDNA used in a BRCA1 test[4]) is much greater. How can educators avoid these risks without teaching DNA sequencing and genetic testing in the abstract, i.e. without experimental components and laboratory exercises? Should they avoid teaching these subjects completely because of genetic testing patents?

The vagueness of the existing experimental use exception in patent law does little to assuage these concerns. At least one court has concluded that any financial gain by a research university presumes against a finding that the university's use of a patent was protected as experimental.[5] Without clarification, this standard suggests absurd results if applied to smaller educational institutions. For example, can public schools perform genetic tests as laboratory exercises that private schools cannot? Does Genspace, which charges a nominal fee for equipment costs and instruction, risk liability for patent infringement by helping schoolchildren sequence their own genotypes or by coaching high school or college students in genetic competitions?

Current research on genetic testing patents has concluded that "patents on research tools can reduce lines of research and retard technological development."[6] We lack a means to measure how much science education has already been chilled by these patents, but without a recognized educational exemption we can be certain that the chill will spread.

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[3] Rochelle C. Dreyfuss & James P. Evans, *From Bilski Back to Benton: Preemption, Inventing Around, and the Case of Genetic Diagnostics*, 63 STAN. L. REV. 1349, 1367 n. 102 (2011); Sec'y Advisory Committee, *supra* note 3 at 31.
[4] *Compare Assoc. for Molecular Pathology v. USPTO*, No. 2010-1402, *slip op*. at 38 (Fed. Cir. 2011).
[5] *Madey v. Duke University*, 307 F. 3d 1351 (Fed. Cir. 2002).
[6] Dreyfuss & Evans, *supra* note 4 at 1375.

Conclusion

Many genetic tests do not require extensive training or advanced facilities to perform. The relevant processes can be learned in the course of an afternoon by an eager student, and the equipment required costs no more than a few thousand dollars.[7] The limited resources required places such research well within the reach of nearly every school, non-profit science center, and motivated individual. This is not the case for antibody-based tests, which have been suggested by some as a replacement for nucleic acid-based tests. If the progress of science and science education is to continue, students, teachers, and the intellectually curious must not have to fear patent infringement or exhorbitant licensing fees.

Additionally, what if due to insurance reasons he/she cannot afford to have the test performed by a licensed lab, but it is simple enough to perform on him/herself with complete accuracy (Myriad's BRCA test falls in this category)? We do not sympathize with the inhumane viewpoint of people who argue that since the current patents will expire within the next 20 years, or alternately because this is 'a problem with the insurance system not the patent system' that nothing should be done.

We have urged recognition for an exemption that permits individuals to perform patented genetic tests on their own genotypes, and a supporting exemption for educators who teach individuals how to perform these tests. To be clear, we do not otherwise advocate an expansion of existing rights for one individual to perform a patent for commercial use, other than to the extent that independent research or education may be construed as such a use.

We urge the Commissioner to issue a clear statement protecting individual rights to perform independent genetic research and for educators to provide scientific instruction, regardless of any conflicting patent. Without public recognition of these rights, genetic testing patents may prevent millions of Americans from understanding their own unique identity and their place in our common human heritage.

Respectfully,

Ellen D. Jorgensen, Ph.D.
Co-founder & President

Oliver Medvedik, Ph.D.
Co-founder, Director of Scientific Programs

[7] Ritchie S. King, *When Breakthroughs Begin at Home*, N.Y. TIMES, Jan. 16, 2012, available at: http://www.nytimes.com /2012/01/17/science/for-bio-hackers-lab-work-often-begins-at-home.html.