Gene patents and licensing: Case studies prepared for the Secretary's Advisory Committee on Genetics, Health, and Society

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Abstract: Researchers at the Center for Public Genomics at Duke University analyzed how patenting and licensing affect clinical access to genetic testing in the United States. The research was requested by the Secretary's Advisory Committee on Genetics, Health, and Society. Conditions studied were breast and ovarian cancers, colon cancers, Alzheimer disease, cystic fibrosis, hearing loss, hereditary hemochromatosis, long QT syndrome, spinocerebellar ataxia, Tay-Sachs disease, and Canavan disease. ***Genet Med* 2010:12(4):S1–S2.**

Key Words: *patents, intellectual property, Secretary's Advisory Committee on Genetics, Health, and Society, breast cancer, colorectal cancer, colon cancer, Lynch syndrome, FAP, familial adenomatous polyposis, BRCA, APC, MSH, Myriad Genetics, genetic testing, Alzheimer disease, Athena diagnostics, cystic fibrosis, University of Michigan, University of Toronto, Hospital for Sick Children, CFTR, long QT syndrome, arrhythmia, University of Utah, hearing loss, deafness, microarray analysis, hemochromatosis, HFE, spinocerebellar ataxia, ataxia, Tay-Sachs disease, Canavan disease, patient advocacy*

The case studies that follow were commissioned by the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) and US Department of Health and Human Services.

In 2006, the SACGHS contacted the Center for Public Genomics (CpG) at Duke University for help in analyzing how patenting and licensing affect clinical access to genetic testing in the United States. SACGHS's interest grew largely from public controversies about breast and ovarian cancer, Canavan disease, and other "gene patents" associated with clinical genetic testing. Controversies in the 1990s led to policy reports around the world.[1–10] In mid-2006, SACGHS appointed a task force to address the impact of patenting and licensing on clinical access to genetic testing, chaired by James P. Evans of the University of North Carolina. The 2006 National Research Council report, "Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health," reviewed several cases of clinical genetic testing, but it mainly addressed whether patents affected genomic and proteomic research.[5] SACGHS decided to delve more deeply into intellectual property's effects on clinical access to genetic testing.

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Disclosure: The authors declare no conflict of interest. See Acknowledgments for details.

The views presented here are the views of the authors and do not necessarily represent the views of the US Environmental Protection Agency.

DOI: 10.1097/GIM.0b013e3181d694b0

In January 2007, the graduate and professional student capstone section of Duke's Health Policy Certificate program made the task force its client. Students enrolled in Professor Christopher Conover's course were joined by Dr. Subhashini Chandrasekharan of the CpG, Julia Carbone, a LLM student at Duke Law, and Dr. Robert Cook-Deegan. Students in the class were as follows:

- Christopher DeRienzo, MD, MPP, now a pediatric resident at Duke University Medical Center;
- Melissa Fiffer, MEM, now at the Stratospheric Protection Division, US Environmental Protection Agency;
- Tamara James, MLS, now the Ergonomics Director, Occupational and Environmental Safety Office, Duke University and Health System;
- Emily Pitlick, JD, now at Van Ness Feldman, P.C.;
- Patrick Sobczak, JD;
- Gabriela Zabala, MALS.

The capstone students prepared an analytical framework and "case studies" and presented preliminary findings to the SACGHS task force in March 2007. Two more case studies were added through the CpG summer student research program, including a study by undergraduate Katie Skeehan on testing for Alzheimer disease and by University of North Carolina graduate student Ashton Powell on spinocerebellar ataxia (SCA). CpG revised and augmented the student reports with patent landscapes and stakeholder interviews. From late 2006 until March 2009, CpG researchers studying the histories of seminal genomic technologies began working almost exclusively for SACGHS and its task force. Both the project officer for the grant that funds the CpG and the National Human Genome Research Institute Director were enthusiastic about having outputs of the CpG's research be inputs to SACGHS and agreed with reorienting the research priorities of the CpG to accommodate the needs of SACGHS.

The CpG-SACGHS collaboration depended on the work of many people for several years. The case studies also leveraged the network of experts associated with the grant. The SACGHS case studies were critiqued at annual CpG retreats, CpG monthly investigator meetings, and Duke-wide Institute for Genome Sciences and Policy (IGSP) lectures. Preliminary findings were presented at national meetings: the international Ethical, Legal and Social Implications (ELSI) conference in Cleveland (May 2008), Capitol Hill event in the Longworth House Office Building in October 2008 (in collaboration with McGill University), and poster sessions of 2008 meetings of the Association of University Technology Managers and the American Society of Human Genetics.

The CpG case studies were released in March 2009 as a 300-page appendix to the SACGHS "Public Consultation Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests." The report was

discussed at the SACGHS's October 8–9 meeting in 2009, when the case studies were referred to during the debate.[11] With the exception of updates to prices and patent information, as noted in the text, and to the long QT and breast and ovarian cancer case studies and formatting changes, the case studies are published in *Genetics in Medicine* in the same form as they were released for public comment.

ACKNOWLEDGMENTS

The case studies discussed were carried out under Grant P50 003391, co-funded by the National Human Genome Research Institute and US Department of Energy, and supplemented by funding from The Duke Endowment.

The case study authors have no consultancies, stock ownership, grants, or equity interests that would create financial conflicts of interest. The Center for Genome Ethics, Law and Policy accepts no industry funding. Robert Cook-Deegan is listed on the British Medical Journal roster of physicians who have pledged to remain independent of industry funding, (http://www.tseed.com/pdfs/bmj.pdf); more details about how the case studies were done are noted in a 29 July 2009 letter to the Secretary's Advisory Committee on Genetics, Health, and Society (http://www.genome.duke.edu/centers/gelp/documents/SACGHS Responsetopubliccomments.pdf).

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