

The Genomic Research and Accessibility Act (H.R. 977)

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GENE PATENTS HAMPER HEALTH CARE & RESEARCH

Gene Patents Discourage the Sharing of Information

- Research into disease cures is impeded when the holder of a patent on the disease gene prohibits other scientists from undertaking research involving that gene. Patent holders have shut down genetic disease research projects at major universities.
- 28% of geneticists were unable to duplicate published results because other scientists refused to share information, data or materials.
- 47% of geneticists have been denied requests from other faculty members for information, data, or materials regarding published research.
- When geneticists were asked why they intentionally withheld data, more than 20% listed the need to protect the commercial value of their results.
- One in every five medical scientists delayed publication of research results for at least half a year in order to protect financial interests.
- Scientists directly engaged in the commercialization of their research were three times more likely to delay publication and twice as likely to refuse to share information as those who were doing basic work.
- Data withholding is affecting the training of the next generation of scientists. Almost one fourth of doctoral students and postdoctoral fellows reported being denied access to information, data and materials.
- Among the life scientists, geneticists were the most likely to withhold data.

Drug Patenting is Not the Appropriate Analogy

Drug development requires a greater economic incentive than gene discovery and there are fewer social, economic, and public health costs of granting a drug patent than a gene patent.

- Other researchers can create alternatives to drugs and devices, but there are no alternatives to the patented human genes in genetic diagnosis and gene therapy.
- The patent incentive is not necessary financially because, unlike with drug development, no lengthy and expensive clinical trials are necessary when a gene is discovered. Once a disease gene is identified, testing can begin almost immediately.
- There is no costly FDA approval process for genetic testing, unlike for drug approval (The FDA does not regulate clinical services of genetic tests.)

- The discovery of genes has received vast public funding, as opposed to the development of drugs which is undertaken primarily with private funds. In 2000 alone, more than \$1.8 billion of taxpayer money was spent on genomics. This means the public pays twice – once to fund the research to discover the gene and then again for the high royalty cost when a person needs to have a blood test to analyze his or her version of the patented gene.

Gene Patents Diminish the Accessibility of Genetic Tests

- The Canadian province of British Columbia stopped paying for genetic breast cancer testing because their health care system could not afford what the patent holder, Myriad Genetics, charged.
- The very people whose genes were patented may not be able to afford the test created using their bodily material, or even worse, find that a company has decided to quash entirely a test related to their condition.

Gene Patents Can Impede the Delivery of Health Care

Certain gene patent holders do not let anyone else test for “their” gene, making it more difficult to find mutations than if many labs were testing.

- In countries where the Alzheimer’s gene and the hemochromatosis gene were not patented, researchers found previously unknown mutations which could be used to diagnose people who would not otherwise have known about their condition.
- Patents have caused one in four laboratories to abandon a clinical test that they had developed.
- Over one-half of laboratories surveyed reported that they had not developed a test for fear of running afoul of patent law.
- Since certain genes, such as the breast cancer genes, have been patented, university researchers have been forced to stop their research due to stringent licensing agreements.

Companies now also patent disease-causing bacteria and viruses. The genome of the virus that causes Hepatitis C, for example, is owned. This can lead to major problems:

- It may lead to wasteful duplication if another researcher is trying to uncover the same sequence but does not know that another researcher is quietly patenting it.
- If someone else wants to introduce inexpensive, quick public health testing for a common infectious disease, the patent holder can prevent it.

Gene patents also hamper pharmacogenomics (a biotechnological science that combines the techniques of medicine, pharmacology, and genomics and is concerned with developing drug therapies to compensate for genetic differences in patients which cause varied responses to a single therapeutic regimen – think specialized medicine specific to a person’s genetic makeup, for one size does not always fit all).

- For example, a pharmaceutical company has filed for a patent on a genetic test to determine the effectiveness of one of its drugs. But the company says it will not develop the test, or let anyone else develop it. Such a test would cause the company to lose customers (since people for whom the drug is not effective would no longer buy it).

The Problem of Multiple Rights Holders

- A researcher who wants to find a cure for breast cancer, for example, would have to negotiate with not only the patent holder for the full BRCA1 and BRCA2 genes, but with all of the other patent holders who had discovered and patented any of the hundreds of other mutations in that gene.
- If a particular patent holder wanted to be the entity to find a gene therapy for the disease at issue and did not want any other researcher to have that chance, that patent holder could refuse to negotiate.
- If a company, state agency, or not-for-profit group wants to include several genetic tests in a panel it offers to the public, it may be prohibitively expensive if each disease gene has been patented and its owner demands royalties or has already exclusively licensed it to someone else.
- The United States does not have an explicit research exception in its patent law that would allow basic research to progress without requiring patent permissions. In contrast, European patent law allows researchers in both commercial and noncommercial setting to use a patent invention in their research without violating the patent.

H.R. 977 is pro-business

- Competition breeds innovation.
- Enacting the Genomic Research and Accessibility Act does not hamper invention, indeed, it encourages it.
- Medical innovation and economic advancement will occur if the study of genes is allowed to happen unabated.
- Incredible manifestations of intellectual property will result: medicines, machines, processes – most deserving of recognition, some potentially life-saving, and all worthy of a patent.

Relevant Sources

Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 Nature Reviews Genetics 803 (2002).

- Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 Hous. J. Health Law & Pol'y 65 (2002).
- Geeta Anand, *Big Drug Makers Try to Postpone Custom Regimens*, Wall Street Journal, June 18, 2001 at B1.
- Kimberly Blanton, *Corporate Take-Over Exploiting the US Patent System, A Single Company Has Gained Control Over Genetic Research and Testing for Breast Cancer*, The Boston Globe, February 24, 2002, at 10.
- David Blumenthal, Eric Campbell, Manjusha Gokhale, Recai Yucel, Brian Clarridge, Stephen Hilgartner, Neil Holtzman, *Data Withholding in Genetics and the Other Life Sciences: Prevalences and Predictors*, 81 Acad. Med. 137 (2006).
- David Blumenthal, Eric Campbell, M.S. Anderson, N. Causino, K.S. Louis, *Withholding Research Results in Academic Life Sciences: Evidence of a National Survey of Faculty*, 227 JAMA 1224 (1997).
- Declan Butler and Sally Goodman, *French Researchers Take a Stand Against the Cancer Gene Patent*, 413 Nature 95 (2001).
- Eric G. Campbell, Brian Clarridge, Manjusha Gokhale, Lauren Birenbaum, Stephen Hilgartner, Neil Holtzman, David Blumenthal, *Data Withholding in Academic Genetics*, 287 JAMA 473 (2002).
- Mildred Cho, Samantha Illangasekare, Meredith Weaver, Debra Leonard, Jon Merz, *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. of Molec. Diag., February 2003.
- Linda J. Demaine and Aaron Xaxier Fellmeth, *Reinventing the Double Helix: A Novel and Non-Obvious Reconceptualization of the Biotechnology Patent*, 55 Stan. L. Rev. 303 (2002).
- Rebecca S. Eisenberg, *Patents and Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017 (1989).
- Michael A. Heller and Rebecca Eisenberg, *Can Patents Deter Innovation? The Anti-commons in Biomedical Research*, 280 Science 698 (May 1, 1998).
- Jonathan Kahn, *What's the Use? Law and Authority in Patenting Human Genetic Material*, 14 Stan. L. & Pol'y Rev. 417 (2003).
- Elaine M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 Tenn. L. Rev. 707 (2004).
- Jon F. Merz, Antigone G. Kriss, Debra G. B. Leonard, Mildred K. Cho, *Diagnostic Testing Fails the Test: The Pitfalls of Patents are Illustrated by the Case of Haemochromatosis*, 415 Nature 577 (2002).
- Jon Merz, *Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine*, 45 Clin. Chem. 324 (1999).

Christine Vogeli, Recai Yucel, Eran Bendavid, Lisa Jones, Melissa Anderson, Karen Seashore Louis, Eric Campbell, *Data Withholding and the Next Generation of Scientists: Results of a National Survey*, 81 Acad. Med. 128 (2006).