

The Journal of Health Care Law & Policy
Volume 6, Number 2

“At the Crossroads – Public/Private Priorities Concerning Access to Genetic Information”

Please note that the following abstracts are the work-product of journal staff members and are not the work of the authors themselves. If you wish to access the full text of any of these articles, they are available electronically on the Westlaw and Hein Online research databases, or can be obtained in hard copy by contacting the William S. Hein Co., Inc., at 1-800-828-7571 or at <http://www.wshein.com>.

Navigating Uncharted Waters: Intellectual Property Rights Surrounding Genomics Research & Development Information (Foreword)

Lawrence M. Sung, J.D., Ph.D.

In recent years there have been tremendous gains in the area of genetic research. However, with these enormous scientific advances comes “uncharted territory” in the area of intellectual property and health care law. In his foreword, Sung outlines areas that will need further development to keep pace with scientific progress. Included is the increasing complexity of patent law for advances in genetic research, especially with regard to openness in communication between scientists balanced against protecting commercial interests. Also, how much of an individual’s genetic information should be shared with insurance companies and other entities should be balanced against openness as well. Finally, through dialogue the scientific and legal community can come to resolve some of these issues.

The Potential Impact of Genetic Sequencing on the American Health Insurance System

Frederick Levy, M.D., J.D. and Joseph E. Lawler, MD, Ph.D.

There have been several very significant advances in recent years in the area of genetics. Given that the future may include very in depth genetic information, the authors, Dr. Frederick Levy and Joseph F. Lawler present a model for health insurance companies that includes screening guidelines are tailored to an individual policy holder, and posits that there are practical reasons why an insurer would not use this genetic information in a discriminatory manner. In Part II of the article, the authors present the design of the health insurance model, in which policies are personalized to an individual’s genetic predispositions. Part III described the current state of legislative and common law, both of which have been slow to respond to these genetic advances. The fourth part of the article explains some of the privacy issues that may arise in light of these advances. Finally, the authors conclude by suggesting that various disciplines will need to work in tandem to realize the potential of these advances.

Public Access Versus Proprietary Rights in Genomic Information: What is the Proper Role of Intellectual Property Rights?

Janice M. Mueller, J.D.

Bioinformatics is a junction of biology and information technology, which was developed to organize and analyze data obtained from the complete sequencing of the human genome. Although many would prefer to consider the completion of the human genome project as a major advance that would benefit all and be owned by no one, there have already been intellectual property rights obtained for genes and gene fragments by entities in the private sector. Since this is the case, it is important to develop a framework that would ensure free access to the genetic data for the purposes of research and scientific advancement, while maintaining an economic incentive to invest in these research projects. In her article, Professor Mueller examines the role of intellectual property rights in bioinformatics. The first part of the article provides an overview of the different forms of intellectual property rights that are relevant to the field of bioinformatics. The second part of the article focuses on statutory law and the utility requirement of patentability as related to bioinformatics inventions. The third part of the article explores possible responses to the public access problem. The fourth part concludes by discussing the role of intellectual property rights as bioinformatics advances.

Data-Sharing and Data-Withholding in the Genetics and the Life Sciences: Result of a National Survey of Technology Transfer Officers

Eric G. Campbell, Ph.D. and Eran Bendavid, M.D.

The philosophy of the scientific world is to allow open sharing of information to promote advances in science. However, in the last several years the science has become commercialized, and as a result, universities and labs are less likely to share information. A common reason is to protect publication. In their study, Drs. Campbell and Bendavid investigate the attitudes of technology transfer officers (TTO's); individuals working for universities and labs that manage transfer of information from their employer institution. The study demonstrated first, that TTO's are more likely to withhold information until after publication. Second, that TTO's feel scientists should be more careful when sharing information to protect publication interests. Third, most TTO's work at institutions do not have policies relating to information sharing. Finally, the study showed that publication may hurt a university's commercial interests, since the information is dispersed amongst competing researchers and the public at large.

Piercing the Academic Veil: Disaffecting the Common Law Exception to the Patent Infringement Liability and the Future of a Bona Fide Research Use Exception After *Madey v. Duke University*

Lawrence M. Sung, J.D., Ph.D. and Claire Maisano

Although the image of scientific research includes the free exchange of ideas between researchers, more and more scientists are finding that this image has limitations; namely that free

exchange of ideas is limited by patent infringement liability. 35 U.S.C. § 271(e)(1) provides a limited exception to patent infringement liability for any activity reasonably related to the preparation and submission of an application for federal regulatory approval. However, this exception is more limited than is perceived by the scientific community. In their article, Professor Sung and Claire M. Maisano explore patent law jurisprudence relevant to a research use exemption, both statutory and common law. The authors also provide a comparative assessment of research use exceptions in laws of other countries. Finally, the authors consider the possibility of a broader statutory research use exception. The authors conclude that a balance between competing interests of investors and researchers is necessary to protect the interests of both.

Contrary to First Impression, Genes are Patentable: Should there be Limitations? (Comment)

Amanda S. Pitcher

The Human Genome Project was designed in 1988 to discover the entire DNA sequence of the genome. The U.S. Government's hope was that the discovery of the entire genome will lead to the new development of new methods of medical treatment. The U.S. Patent and Trademark Office (USPTO) has issued several thousand gene patents in recent years. Pitcher provides an overview of the patent system and its underlying policies, and the statutory requirements that must be met for a patent to be issued to a gene sequencer. After examining the legality of gene patenting, Pitcher argues that because the benefits arising from gene patents overcome the objections to their patenting, Congress should impose compulsory licensing on gene patent owners in order to promote continued research and development.