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Navigating Unchartered Waters: Intellectual Property Rights Surrounding Genomics Research & Development Information

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FOREWORD

NAVIGATING UNCHARTED WATERS: INTELLECTUAL PROPERTY RIGHTS SURROUNDING GENOMICS RESEARCH & DEVELOPMENT INFORMATION

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The completion of a working draft of the human genome sequence two years ago will, no doubt, prove to be an integral chapter in a story of extraordinary technological achievement– a story based on the continued revelation of genetic information. The story, however, is unfinished and the outcome is uncertain. Many issues have yet to be addressed, in particular, the question of access.

There is a vast amount of genetic data being generated through the efforts of various public and private research institutions. Who is allowed access to the genetic data? Who regulates this access? Who pays for and who benefits from such access? The answers to these questions must be answered before the rest of the story can be written.

On October 21, 2002, the Intellectual Property Law Program and The Law and Health Care Program of the University of Maryland School of Law co-hosted an interdisciplinary symposium entitled, "At the Crossroads–Public/Private Priorities Concerning Access to Genetic Information." This conference focused on the business, legal, scientific and social implications of regulating access to genetic data. In addition, the symposium provided a forum to explore the development of a consensus model for balancing the benefits of free and unfettered public access to genetic information with those of protecting private investment-backed expectations regarding genetic research. The program drew from the combined insights of international scholars in molecular genetics and bioinformatics, intellectual property law, and bioethics, as well as from various perspectives of leaders in the biotechnology industry.

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I. HUMANITY'S GREATEST GIFT PRESENTS HUMANITY'S GREATEST CHALLENGE

Scientists' ability to unmask nature's design, through the automated sequencing of the genetic code using evolving techniques, continues to capture the media spotlight. Indeed, the endeavor to understand the human condition, which is fueled by the desire to enhance and prolong life, marks each year with discoveries of great significance. On February 21, 2001, the world awoke to the defining news that a milestone in genetic knowledge was achieved, which is arguably unrivaled by any other previous announcement.[1] The scientific research teams dedicated to deciphering the precise structural nature of the chemicals that encode the design of the human organism announced the release of their long anticipated findings– the nucleotide sequence of the human genome.[2]

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1. *See, e.g., Early Edition: Scientists Set to Announce Major Advances in Mapping the Human Genome* (CNN television broadcast, Feb. 12, 2001), LEXIS, News Library, Transcripts ("[I]n just three hours, we're going to hear what could be the beginning of a revolution in the practice of medicine. An announcement regarding the mapping of all the genes in the human body will be made in Washington."); *Today: Human Genome Decoded* (NBC television broadcast, Feb. 12, 2001), LEXIS, News Library, Transcripts ("This morning details on what may be the most amazing scientific accomplishment ever, the mapping of the human genome. Last June, scientists on competing teams announced they had done it, and today they are releasing their results, and it could revolutionize the future of medical care."); *World News This Morning: Map of Human Genome Debuts with Some Big Surprises* (ABC television broadcast, Feb. 12, 2001), LEXIS, News Library, Transcripts ("History will have to judge, of course, but scientists say they may be at a turning point comparable to Copernicus figuring out the layout of the solar system or Darwin beginning to understand how plants and animals evolved."); *The Early Show: Two Rival Studies Offer the First Detailed Look at Most of the Human Genetic Code* (CBS television broadcast, Feb. 12, 2001), LEXIS, News Library, Transcripts ("We've been trying in the 20th century to try to treat disease without even knowing what the parts were, without knowing what was wrong in diseases like diabetes or asthma or hypertension. It'd be like bringing your car to an auto mechanic who didn't know what was under the hood, didn't know the parts."); *see also* Clive Cookson, *A Glimpse of the Secrets of Life: The Results of the Human Genome Project Show Unexpected Layers of Complexity in our Genes*, FIN. TIMES (London), Feb. 12, 2001, at 21, LEXIS, News Library, Major World Newspapers ("Eight months ago, Bill Clinton and Tony Blair linked up to proclaim one of science's greatest achievements: decoding the human genome or 'book of life.' But that public relations spectacular was not supported by research data or conclusions. This week scientists get their first look at the evidence, with the official publication of the human genome sequence in the journals Nature and Science."); *China on Par with Developed Countries in Genome Research: Experts*, XINHUA NEWS AGENCY (Beijing), Feb. 12, 2001, LEXIS, News Library, Beyond Two Years ("The latest map and preliminary conclusion on the human genome by experts from China and five developed countries indicate China is on a par with the developed countries in this field . . . . [T]he progress, unveiled late Monday by international sciences news weekly Science and Nature, is the result of international cooperation. The research demonstrates the strength of China, the only developing country allowed to join the project, in this advanced research field . . . .").

2. *See* Elizabeth Pennisi, *The Human Genome*, 291 SCI. 1177, 1178 (2001) ("Just obtaining the sequence is a phenomenal achievement, one that many researchers did not believe possible 15 years ago . . . . Spelling out the entire sequence, all 3 billion or so chemical letters that make up DNA along each chromosome would fill tomes equivalent to 200 New York City phone books . . . . Perhaps most humbling of all is the finding . . . that humans have 32,000 genes, give or take a few thousand.").

For even the most casual observers, the accomplishment underlying this report was earthshaking.[3] Even for those who had closely monitored the progress of this project throughout its years of intensive effort, the publication of the human genome sequence was no less heralded. Indeed, the editors of *Science*, one of the two leading scientific journals, pronounced it a "historic moment for the scientific endeavor."[4] The message to the scientific community, however, also appeared to reflect a tenor of underlying concern.

> Humanity has been given a great gift. With the completion of the human genome sequence, we have received a powerful tool for unlocking the secrets of our genetic heritage and for finding our place among the other participants in the adventure of life . . . . It should be no surprise that an achievement so stunning, and so carefully watched, has created new challenges for the scientific venture.[5]

The process of the discovering of our genetic code, from its inception, has fostered coincident public scrutiny and concern, which included portents of privacy loss, genetic discrimination and eugenics.[6] Perhaps most controversial, however, are the issues of ownership and exclusivity obtainable, through patent protection, to aspects of the human genome.[7] The public debate aside, the federal courts,

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3. *See* Leslie Roberts, *Controversial from the Start*, 291 SCI. 1182, 1182 (2001) ("The human genome: the crown jewel of 20th century biology, heralded at the White House, plastered on the covers of countless magazines–and at last spelled out today in intricate detail in both *Science* and *Nature*. Deciphering this string of 3 billion A's, T's, G's, and C's is being hailed as an achievement that will usher in a new era of biology and even alter our understanding of who we are.").

4. *See* Barbara R. Jasny & Donald Kennedy, *The Human Genome*, 291 SCI. 1153, 1153 (2001) (commemorating the contemporaneous publications of the human genome sequence in *Science* by J. Craig Venter et al. of Celera Genomics, a private enterprise, and in *Nature* by the International Human Genome Sequencing Consortium, a publicly-funded international cooperative of laboratories led by Francis Collins).

5. *See id.* (indicating, as important considerations, aspects of "access to all the data needed to verify conclusions" and "protection against piracy . . . [to] enable other proprietary data to be published after peer review.").

6. *See* Jeremy A. Colby, *An Analysis of Genetic Discrimination Legislation Proposed by the 105th Congress*, 24 AM. J.L. & MED. 443, 443-44 (1998) ("[G]enetic information may also result in a world characterized by genetic discrimination and genetic determinism. Although genetic information will be used to develop revolutionary treatments, such as gene therapy and other molecular medicine, it will also bring genetic discrimination and heretofore unrealized invasions into the privacy of our genetic codes.").

7. *See* Eliot Marshall, *Sharing the Glory, Not the Credit*, 291 SCI. 1189, 1191 (2001) (reporting the stern reaction by scientists to the negotiations between Celera and *Science* of "a balanced plan, requiring Celera to release data freely to academics but allowing the company to protect its database by requiring readers to obtain access at a company site and register as academic or commercial users."). Of course, the U.S. patent system has supporters and detractors alike. Nevertheless, its significance, positive or negative, to the business community appears clear. *See* John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 VAND. L. REV. 2099, 2100 (2000) ("Patents are big business. Individuals and companies are obtaining far more patents today than ever before. Some simple calculations make it clear that companies are spending over $5 billion a year obtaining patents in the U.S.– to say nothing of the costs of obtaining patents elsewhere, and of

principally the U.S. Court of Appeals for the Federal Circuit,[8] and the U.S. Patent and Trademark Office have both attempted to provide guidance on the intellectual property rights that might impact such matters involving the human genome and other genetic data. These efforts, however, have met with lackluster support at best from patent law practitioners and other commentators, as well as the general public.[9]

In recent days, public debate in this regard has focused on the proper scope, if any, of general patent protection for genetic discoveries, and specifically for expressed sequence tags and single nucleotide polymorphisms. Two concerns prevail. The first relates to the challenge, pursuant to the written description requirement of the patent law, to patent coverage of inventions pertaining to genes or gene fragments where the applicant has failed to disclose the corresponding nucleotide sequence information. The second involves whether isolated and purified nucleic acid fragments with no known association or other functionality can satisfy the patent law requirement of utility as well as written description.

Given the reactive nature of the patent system, particularly in a technical art such as biotechnology where the law today deals with the potentially decades-old science, the legal issues have centered on early research work in recombinant protein production and genomics.[10] With the human genome sequence in hand, scientists and other interested members of the public recognize that the practical applications will likely include better, faster, cheaper routes to drug discovery and

licensing and enforcing the patents. There are a number of reasons why patenting is on the rise; primary among them are a booming economy and a shift away from manufacturing and capital-intensive industries towards companies with primarily intellectual assets. But whatever the reason, it is evident that many companies consider patents important.").

8. The Federal Circuit has exclusive jurisdiction of appeals in civil actions across the country that arise under the patent statutes. *See* 28 U.S.C. § 1295 (1994) (vesting the Federal Circuit with exclusive jurisdiction in patent appeals from final judgments and orders of the U.S. district courts and the U.S. Court of Federal Claims, from decisions of the Board of Patent Appeals and Interferences of U.S. Patent and Trademark Office, from decisions of Commissioner of Patents and Trademarks, and from decisions of the U.S. International Trade Commission); *see also* S. REP. NO. 275, 97th Cong., 2d Sess. 2 (1981), *reprinted in* 1982 U.S.C.C.A.N. (96 Stat.) 11, 12 (describing the legislative rationale behind the establishment of the Federal Circuit with the enactment of the Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25, 37 (codified as amended at 28 U.S.C. § 1295)).

9. *See* Jerry Knight, *Biotech Stocks Tougher to Unravel than Genome*, WASH. POST, Feb. 19, 2001, at E01, 2001 WL 2545185, (warning about investment in biotechnology companies because "[t]heir science is so complex, their business strategies so unpredictable, their path to profitability so uncertain–to say nothing of so long–that it's impossible to calculate what each stock is worth or which is better to buy.").

10. *See* Courtney J. Miller, *Patent Law and Human Genomics*, 26 CAP. U. L. REV. 893, 894 (1997) ("The genomics industry is a complex and frustrating combination of philanthropy and commercialism, science and law. The basic premise of sequencing the human genome is that such a venture will benefit humankind, but the importance of protecting the significant financial and physical investments required to sustain the effort have resulted in the need for definitive federal legislative guidelines concerning the intellectual property generated as the genomics industry matures.").

advances in medical practice.[11] However, a sobering reality has emerged as to how daunting the magnitude of this task might truly be.

When it comes to human genetic makeup, there is an incredible amount of chaff to separate from the wheat. Thus, how quickly medical researchers achieve their goals may depend on how long it takes to understand the exploding storehouses of genetic information. The true race now appears not to have been who first maps every last stretch of human DNA, but who can most successfully identify candidates for effective drug and gene therapy based on genetic information with little, if any, known biological significance.

This progress depends in large part on other scientific fields, that of bioinformatics (once better known as computational biology) and proteomics.[12] The legal ramifications of intellectual property protection in this developing research area will probably take years to manifest, but might engender as much, if not more, public debate as that which presently surrounds biotechnology patents.[13] Possibly compounding the problem will be the likely overlap in patentability concerns with computer software programs at the heart of bioinformatics and

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11. *See* Sara Dastgheib-Vinarov, *A Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTELL. PROP. L. REV. 143, *158-59 (2000), WL 4 MARQIPLR 143 ("In the new millennium, computational and molecular techniques allow scientists to accomplish what was once deemed impossible. Some of these techniques include designing optimum DNA probes for PCR and comparing three-dimensional protein secondary structure of various species with their mRNA sequences on a computer. These techniques, which reduce experiment times from days to minutes, have made most traditional molecular biological procedures obsolete.").

12. *See* Mark J. Stewart, *The Written Description Requirement of 35 U.S.C. § 112(1): The Standard after Regents of the University of California v. Eli Lilly & Co.*, 32 IND. L. REV. 537, 555 n.153 (1999) ("The development of bioinformatics is beginning to manage the increasing amount of genetic sequence information that is becoming available. Bioinformatics provides ways to analyze DNA and protein sequences and make predictions regarding structure or function relationships.") (citing Andreas D. Baxevanis & B.F. Ouellette, BIOINFORMATICS: A PRACTICAL GUIDE TO THE ANALYSIS OF GENES AND PROTEINS (1st ed. 1998)); Ronald Cass et al., *Advances in Biomaterials and Devices, and Their Financing*, 6 B.U. J. SCI. & TECH. L. 2, *23 (2000) WL 6 BUJSTL 2, ("How bioinformatics and genetic engineering become important is that one can use information from the human genome project. The idea is then to use this information to help predict what functions other proteins or other regions of proteins are involved in—not only cellular adhesion but also other cellular roles such as cell death, growth, and migration and differentiation."); David Malakoff & Robert F. Service, *Genomania Meets the Bottom Line*, 291 SCI. 1193, 1201 (2001) ("Toolmakers, information suppliers, and discovery companies are already looking beyond genomics to proteomics, the latest effort to demystify the functions of the proteins coded for by all those genes. Surveying genes is a good way of finding possible drug targets, the reasoning goes."); Stanley Fields, *Proteomics in Genomeland*, 291 SCI. 1221, 1221 (2001) ("In the wonderland of complete sequences, there is much that genomics cannot do, and so the future belongs to proteomics: the analysis of complete complements of proteins.").

13. *See* Lawrence M. Sung & Jeff E. Schwartz, *Patent Law: Business Method Defense*, NAT'L L.J., Apr. 10, 2000, at B8, *available at* WL 4/10/00 NLJ B8, (col. 1) ("[W]hen the U.S. Court of Appeals for the Federal Circuit issued its decision in *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1093 (1999), the patent law changed to recognize business methods, for the first time, as patentable subject matter . . . . [B]usiness method patents began to create grave concerns over their potentially stifling impact on innovation and commercial competitiveness.").

proteomics applications with the potential for characterization as business methods.[14]

II. PUSHING THE LIMITS OF THE PATENT REGULATORY REGIME: THE LEGAL, ACADEMIC, AND SOCIAL IMPLICATIONS OF EMERGING TECHNOLOGIES

Recently, real-world events have heightened the importance of the intersection between genomic sequencing determinations and bioinformatics technology. For example, prior to September 11, 2001, the Institute for Genomic Research had generally committed its resources to the elucidation of various organisms.[15] However, the Institute's resources have since been retasked to focus on determining the genomic sequence of the possible bioterrorist weapon, *Bacillus anthracis*, the causative agent of anthrax.[16] Despite its tragic toll, the anthrax scare unwittingly revealed the powerful capabilities currently available in genomics and bioinformatics.

This rapid innovation in the genetic arts in turn demands careful consideration of both patent laws and regulations that are implicated by emerging technological discoveries. This examination is particularly important because the technologies involved in genomics and bioinformatics will likely stretch the applicability of the patent regulatory regime well beyond initially contemplated purposes.

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14. *See* Rebecca S. Eisenberg, *Genetics and the Law: The Ethical, Legal, and Social Implications of Genetic Technology and Biomedical Ethics: Intellectual Property at the Public-Private Divide: The Case of Large-Scale cDNA Sequencing*, 3 U. CHI. L. SCH. ROUNDTABLE 557, *564-65 (1996), WL 3 UCHIRLSRT 557:

Despite the growth of the public database, the private databases remain significantly larger. Inasmuch as all the information that enters the public database promptly becomes available in the private databases as well, the public database can never contain more information than the private databases. The private database owners also claim to offer superior products in that they have assembled contiguous fragments into longer sequences, they provide more complete annotations for the sequences, including information about expression in different types of tissue, they provide sequence information from customized cDNA libraries derived from tissue types of interest to their subscribers, and their sequence information comes with high-powered bioinformatics capabilities and user-friendly software. Ironically, Merck's investment in enhancing the public database may have enhanced the value of the private databases as a resource for discovery, not only by contributing further data to make the information in the private databases more complete, but also by creating a deluge of information that enhances the value of the complementary proprietary bioinformatics capabilities that the private database owners offer to their clients. *Id.* (internal citations omitted).

15. Videotape: Dr. Steven L. Salzberg, Keynote Address: *Genomics in the 21st Century: Forensics, Pathogens, and Genetics*, at At the Crossroads–Public/Private Priorities Concerning Access to Genetic Information, Tape 1 of 4 (Oct. 21, 2002) (on file with the University of Maryland School of Law, Thurgood Marshall Law Library).

16. *See generally id.*

Moreover, attempts to obtain patent protection for early stage research products may negatively impact scientific progress.[17] Indeed, in view of their fledgling nature, some of these inventions might carry little or no attendant knowledge about their practical utility.[18] The notion of according patent rights in these instances seemingly would contravene the goal of the patent system to allow exclusivity only when the public obtains the benefit of significant learning regarding an innovative technology.[19] Janice Mueller, one of the contributors to this edition, invites us to examine the tension between constructing patent protection for bioinformatics technologies and ensuring public access to technologies that may possess invaluable public welfare benefits.[20]

Given the rapidity with which technology will be available to affect whole genomic sequencing over the next decade, new models must also emerge to engage these capabilities within the health care regime, and to guard against exploitation by those "with access" to the detriment of the individual. For example, how should new genetic screening capabilities be utilized by health insurers? Drs. Levy and Lawler present a model for health insurance in which screening guidelines are customized to the individual policy holder, delivering superior health care, and yet maintaining profitability for the insurer.[21]

In addition to the complex issues of access stemming from the patentability of emerging biotechnology applications, are those issues surrounding technology transfer. Under the statutory scheme established by the Bayh-Dole Act,[22] academic institutions may elect to retain title to inventions created in the course of federally funded research.[23] These organizations may choose to exploit such inventions by seeking patent protection and licensing this intellectual property to the private sector for commercial development. Furthermore, it is important to note that unlike the laws governing copyrights and trademarks, patent law provides no exemption for academic research similar to the doctrine of fair use.[24]

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17. Videotape: Dr. Francis S. Collins, Address at At the Crossroads–Public/Private Priorities Concerning Access to Genetic Information, Tape 2 of 4 (Oct. 21, 2002) (on file with the University of Maryland School of Law, Thurgood Marshall Law Library).

18. *See generally id.*

19. *Id.*

20. *See generally* Janice M. Mueller, *Public Access Versus Proprietary Rights in Genomic Information: What is the Proper Role of Intellectual Property Rights*?, 6 J. HEALTH CARE L. & POL'Y 222 (2003).

21. *See generally* Frederick Levy & Joseph F. Lawler, *The Potential Impact of Genetic Sequencing on the American Health Insurance System*?, 6 J. HEALTH CARE L. & POL'Y 203 (2003).

22. 35 U.S.C.S. § 203 (2000).

23. Videotape: Second panel discussion moderated by Mary S. Webster, Assistant Professor of Law and Director of the Maryland Intellectual Property Legal Resource Center, at At the Crossroads–Public/Private Priorities Concerning Access to Genetic Information, Tape 2 of 4 (Oct. 21, 2002) (on file with the University of Maryland School of Law, Thurgood Marshall Law Library).

24. My personal contribution to this edition discusses the future of a research use exemption from patent infringement liability. *See* Lawrence M. Sung & Claire M. Maisano, *Piercing the Academic*

In order to gain an appreciation for the effect of intellectual property rights on the collegiality and collaboration behaviors of researchers working in the trenches of innovation, information must be captured and analyzed regarding the attitudes and policies of research institutions regarding technology transfer. Although openness in data-sharing in academic research is a fundamental norm underlying the social structure of academic science, the commercialization of university research through technology transfer has somewhat chilled this openness.[25]

This edition also provides unique insight into the conflicting attitudes and policies of researchers and academic institutions regarding data-sharing and withholding. Drs. Eric G. Campbell and Eran Bendavid at the Institute for Health Policy at the Massachusetts General Hospital unveil the results of a landmark national survey of the senior technology transfer officials of the one hundred most research-intensive universities.[26] Of particular note is the *lack* of consensus among technology transfer officers toward data-sharing and withholding, which the authors note may be a result of conflicting pressures brought to bear on these officers.[27]

The diversity in attitudes among technology transfer officers is but a microcosm of the wide-ranging spectrum of societal views regarding the moral, social and ethical implications of patent exclusivity and use of genetic knowledge.[28] Our two student contributors to this edition engage these social implications, but in differing ways: where one analyzes the spectrum of moral and social considerations in determining they should not impede exclusivity;[29] the other provides a critique of Leon R. Kass' 2002 book, *Life, Liberty and the Defense of Dignity: The Challenge for Bioethics*, reminding us that even in the absence of new regulatory and legislative constraints on the use of genetic information, the scientific community has refrained from recklessly unleashing new technologies.[30]

Veil: Disaffecting the Common Law Exception to Patent Infringement Liability and the Future of a Bona Fide *Research Use Exemption after* Madey v. Duke University, 6 J. HEALTH CARE L. & POL'Y 256 (2003).

25. *See* Eric G. Campbell & Eran Bendavid, *Data-Sharing and Data-Withholding in the Genetics and Life Sciences: Results of a National Survey of Technology Transfer Officers*, 6 J. HEALTH CARE L. & POL'Y 241 (2003).

26. *See generally id.*

27. *Id.*

28. Videotape: Third panel discussion, moderated by Barbara Fuller, Chief of Policy, Education and Outreach at the National Human Genome Research Institute, at At the Crossroads–Public/Private Priorities Concerning Access to Genetic Information, Tape 3 of 4 (Oct. 21, 2002) (on file with the University of Maryland School of Law, Thurgood Marshall Law Library) (discussing the ethical and social implications of exclusivity in genetic knowledge).

29. *See generally* Amanda Pitcher, *Genes Are Patentable, Contrary to First Impression: Should There Be Limitations?*, 6 J. OF HEALTH CARE L. & POL'Y 284 (2003).

30. *See generally* Ella Judge Hayes, *Biotechnology and Human Dignity, A Neessary and Compatible Union*, 6 J. HEALTH CARE L. & POL'Y 304 (2003).

III. SEEKING BALANCE: UNFETTERED ACCESS VERSUS THE PROTECTION OF INVESTMENT-BACKED EXPECTATIONS

In recent days, the perception of intellectual property rights as the driving force of creativity, innovation, and knowledge exchange seems to have lost its luster among the general public. Among those who have a more direct involvement with patent rights, the situation might be no more settled. Patent rights, for example, appear under routine attack– at best as disreputable rent seeking measures and at worst as obstacles themselves to true scientific advancement.

Of course, the ingenuity of a patent system lies with the optimization of social benefit from grants of limited exclusivity. But little disagreement appears to exist that the actual attainment of the proper balance between providing unfettered access and securing investment-backed expectations to new technologies is an illusive matter. The conference, "At the Crossroads–Public/Private Priorities Concerning Access to Genetic Information," was born from the inspiration to engage interdisciplinary perspectives on contemporary social, economic and political realities with regard to biotechnology research and development. Perhaps the success of such a forum lies with the questions raised as much as the answers provided. The University of Maryland School of Law is proud to play a role in enhancing the dialogue in both respects.