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Table of Contents - Issue 1

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CONTENTS

SYMPOSIUM: WHO OWNS YOUR BODY?

SYMPOSIUM EDITOR
LORI ANDREWS

IN MEMORIAM *Lori Andrews* XI

ARTICLES AND REMARKS

WHO OWNS YOUR BODY? A STUDY IN LITERATURE AND LAW	<i>Lori Andrews</i>	3
WHAT I HAVE LEARNED FROM THE REACTIONS TO MY BOOKS	<i>Michael Crichton</i>	13
EXPRESSIVE MINIMALISM AND FUZZY SIGNALS: THE JUDICIARY AND THE ROLE OF LAW	<i>Michele Goodwin</i>	19

The proper role of courts engenders significant debate. Yet, what seems better settled is the principle that courts are the place at which the common law is developed. Its genesis and modifications evolve out of the juridical process and when that process becomes encumbered or deferred to the legislature the role of the judiciary is called into question. This essay makes the case that expressive minimalism too often governs the common law judicial approach to biotechnology. The cases visited in this domain test our capacity to understand whether life is appropriately described as being beyond the definition of property, as well as the disputed assumptions about life being commodifiable, patentable, destroyable, and conscriptable. There are also the circumstances that demand secondary or third party response depending on judicial expression, including what to do when life is stolen, misappropriated or fraudulently acquired. Goodwin argues that rather than motivating legislative action, or imbuing the bench with greater wisdom or information, expressive minimalism in the context of biotechnology will likely send fuzzy signals. Fuzzy signals will not be clear messages to the legislature. To the contrary, fuzzy signals, like those transmitted across cell phones and televisions, discombobulate messages, distort pictures, and ultimately, are difficult to read.

WHAT IS OWED PARTICIPANTS IN BIOTECHNOLOGY RESEARCH?

Julie A. Burger 55

The legal and ethical protections afforded human subjects of research afford individuals who participate in research certain rights. Potential participants must give voluntary and informed consent to participate, they have the right to withdraw from research, they cannot be asked to waive certain rights, and they have the right to choose which studies they will participate in. But researchers, institutions, patient advocacy groups, and ethicists continue to debate how these rules should be applied in the context of genetics research – projects that involve using the individual's tissue or the individual's genetic information, such as gene sequences, and associated medical information. Evidence demonstrates that people have strong feelings and preferences about how their tissue and genetic information is used in research and who has access to it, regardless of whether their name is associated with the sample or information. Not giving due import to individuals' preferences could result in a loss of trust in the research enterprise, and a corresponding decrease in participation in future studies.

UPSTREAM WITHOUT A PADDLE: GENE PATENTING AND THE PROTECTION OF THE “INFOSTRUCTURE”

Seth Shulman 91

The U.S. patent system, designed to protect rights to specific, marketable gadgets, has increasingly over the past few decades granted patents on comparatively abstract and amorphous ideas that stretch the system beyond recognition. Overly broad patents, and patents too far “upstream” from the marketplace, I argue, undermine the patent regime, hamper innovation, and prove exceedingly difficult to adjudicate. Using a series of conceptual and historical analogies, I attempt to assess the patenting of genes and other broad, “upstream” patents from a public policy context, emphasizing, as many are coming to realize, that things work best in the knowledge-based economy when what I describe as the “infostructure”—those seminal information assets needed by all players in a given high-tech sector to compete—are pooled and shared.

GENE PATENTS AND THE PRODUCT OF NATURE DOCTRINE

John M. Conley 109

Gene patents have proven to be enormously controversial, evoking a strong response from many categories of skeptics. Objections have focused on the foreclosure of research, the potential denial of healthcare, or the proper application of the patent laws. Gene patents also tend to trigger an elemental response that lies at the core of almost every objection: You shouldn't be able to patent a gene! This article focuses on the latter point, restating it as a question of legal doctrine: Why is it that the law has routinely treated genes as patentable inventions rather than unpatentable natural phenomena? Part II reviews the basics of patent law, with particular emphasis on patentable subject matter and the long-established product of nature doctrine. Part III discusses the understanding of genetics that is reflected in the patent case law, an understanding that has led the courts and the United States Patent and Trademark Office (USPTO) to find a material distinction between genes as usually claimed in patent applications and their naturally-occurring counterparts. Part IV reviews several recent legal developments that, taken together, may portend some future constraints on the virtually unfettered patentability that genes have enjoyed thus far. Finally, Part V offers some concluding thoughts on the policy implications of these developments.

HUMAN GENE PATENTS: PROOF OF PROBLEMS?

Timothy Caulfield 133

The patenting of human genes has been the focus of intense policy debate. The concerns associated with gene patenting are diverse, ranging from dignity

based critiques to suggestions that patents will drive up the cost of health care. But the two concerns that have generated the most policy attention are that they hurt basic research (also known as the “anti-commons” problem) and access to useful technologies. The goal of this short comment is to question the degree to which existing evidence supports the speculation about these two justifications for patent reform. While the issues associated with gene patents are complex and extend well beyond these two specific issues, their profile within the patent policy debate justifies a consideration of what the available empirical data can tell us about the legitimacy of the concerns. The paper concludes with a discussion of several issues relevant to the interpretation of existing and emerging data.

INDIGENOUS PEOPLES AND GENE DISPUTES

Debra Harry 147

Wary from decades exploitation in the name of science, Indigenous peoples typically approach externally-generated research with caution, and for good reason. Indigenous peoples have been on the receiving end of research carried out in insensitive, and sometimes, harmful ways. Research has historically been a top-down, outside-in process, with Indigenous peoples serving merely as research subjects, with little opportunity for meaningful participation or benefit from the outcomes of the research. Over the past two decades, with the advent of the Human Genome Project and other genetic research projects, there has been a corresponding increase in genetic research projects that put Indigenous peoples front and center of the research process. Geneticists’ interests in Indigenous peoples’ DNA are many. Indigenous peoples’ DNA is sought for medical, behavioral, anthropological, and genetic variation studies. This chapter details many of the experiences Indigenous peoples have had with human genetic research. These stories exemplify the biocolonial nature of this research as it impacts Indigenous peoples.

INTELLECTUAL PROPERTY AND THE POLITICS OF EMERGING TECHNOLOGY: INVENTORS, CITIZENS, AND POWERS TO SHAPE THE FUTURE

Stephen Hilgartner 197

This article argues that there is a mismatch between traditional intellectual property doctrine and the politics of intellectual property today. To examine the nature of the mismatch, I contrast two frameworks that both appear in contemporary debate about intellectual property: the traditional discourse, which focuses on innovation policy, and a newer, less clearly codified discourse that views intellectual property issues from the perspective of the politics of technology. This latter discourse focuses on the challenge of democratic governance in a world where emerging technologies have assumed a central role in constituting the future, raising far-reaching questions about how they should be fitted into social orders. The innovation discourse remains dominant in policy debate, but recognizing the specific features of the politics-of-technology perspective—and presenting its distinctive vision of what is at stake in intellectual property—clarifies the struggles now in play. The politics-of-technology perspective rejects the traditional definition of the boundaries of intellectual property policy; first, because this perspective questions the empirical validity of a bright line distinction between creating technologies and making social choices about them; second, because it sees the traditional cartography as tending to constitute members of the public as “consumers” of prepackaged technologies rather than “citizens” engaged in shaping them; and third, because it has a normative commitment to enabling citizens to exercise voice and choice about emerging technology before irreversible commitments in specific directions are made. In contrast to traditional innovation discourse, the politics-of-technology perspective considers patent policy from a point of view that focuses on questions of democratic governance and political legitimacy.

STUDENT NOTES AND COMMENTS

YOU DON'T OWN ME: RECOMMENDATIONS TO PROTECT HUMAN CONTRIBUTORS OF BIOLOGICAL MATERIAL AFTER *WASHINGTON UNIVERSITY V. CATALONA*

Laura B. Rowe 227

As research using human biological materials has rapidly developed, so too has the debate over the ownership of these highly valuable materials. Most recently, the Eighth Circuit in *Washington University v. Catalona* held that research participants do not retain any ownership interest in the biological materials they contribute to research. This note argues that the misguided *Catalona* decision, in combination with unclear, outdated, and inadequate federal research regulations, has left human contributors of biological material largely unprotected and vulnerable to the goals of researchers, institutions, and biotechnology firms. Accordingly, this note proposes critical amendments to the federal research regulations that will ensure the continued advancement of biomedical research by protecting the human sources who make this research possible.

SERIES LIMITED LIABILITY COMPANIES: A POSSIBLE SOLUTION TO MULTIPLE LLCs Sandra Mertens 271

Although series LLCs are now over eleven years old, they remain mainly theoretical. Only seven states to date have enacted statutes authorizing series LLCs, and the drafters of the recent Revised Uniform Limited Liability Company Act considered and rejected provisions creating series LLCs. Many practicing attorneys continue to use multiple LLCs where a series LLC may be appropriate. This Note examines the general characteristics of series LLCs and state legislation authorizing them, the uncertain state and unanswered questions surrounding this new entity form, and the recent developments in case law and usage of series LLCs. Finally, this Note recommends that state legislators enact enhanced series legislation nation-wide to provide unity and foundation for series LLCs, which will allow attorneys and business owners to reap the benefits of series LLCs.

JUDICIAL ACTIVISM V. JUDICIAL ABDICATION: A PLEA FOR A RETURN TO THE *LOCHNER* ERA SUBSTANTIVE DUE PROCESS METHODOLOGY Brandon S. Swider 315

Amid the fierce battles that take place during the confirmation process of a Supreme Court justice, surprisingly little attention is given to the fact that both sides of the political spectrum generally agree on a matter of profound constitutional importance—namely, the proper level of scrutiny courts are to exact with respect to state and federal legislation. Presently, and for the better part of the last 70 years, the dominant attitude among judicial conservatives and liberals alike is that courts have no authority to strictly scrutinize the overwhelming majority of legislation enacted by state and federal legislatures.

This Comment argues that the Court's current substantive due process doctrine, which traditionally provided an important framework for reviewing the constitutionality of state and federal legislation, not only lacks a solid constitutional foundation but also fails to protect the most basic individual rights and liberties. This Comment discusses the shortcomings of the substantive due process methodology within the context of *Abigail Alliance v. Eschenbach*, which held that terminally ill individuals have no constitutional right to access innovative medicinal treatments that have the potential to preserve and prolong their lives. This Comment concludes that, although the current substantive due process doctrine is highly flawed, the decision in *Lawrence v. Texas* provides a glimmer of hope that one day the Court will reassert the judiciary's responsibility to meaningfully review and scrutinize the constitutionality of state and federal legislation.