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Biotechnology and the Law: Introduction

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This Symposium inaugurates what we hope will become a series of symposia dealing with the legal issues facing the biotechnology industry. Such an ambitious announcement immediately raises a question: Why should the McGeorge School of Law and the McGeorge Law Review devote such attention to biotechnology? Put more simply: Why Biotechnology? Why McGeorge? In fact, the purpose for the articles in this Special Project is to answer these two questions.

This Project begins with an article from my colleague, Raymond Coletta. Professor Coletta is one of the founding members of the Society for Evolutionary Analysis in Law and, as such, a proponent of the law and biology discipline. As with other "law and" disciplines (such as law and economics), law and biology seeks to apply the insights from another field of study (in this instance, biology) to the study of law. Professor Coletta's article focuses on the essential feature of biotechnology, which is that this technology entails altering the natural course of evolution in a radically accelerated time frame. This fact raises profound ethical questions which, in turn, pose fundamental challenges for the law. Some of the resulting ethical and legal questions are evident: Given the vast potential to combat hunger through biotechnological development, and yet the frightening potential danger from unforeseen consequences from such development, what is the appropriate balance of regulation over bio-engineered foods? What are the appropriate uses of the increasing knowledge of the link between a particular individual's genes, and his or her prospect for disease? What are the ethical implications, and, in turn, appropriate legal limitations, on use of biotechnology to engineer desired traits in human beings? Professor Coletta's paper, however, goes beyond these difficult issues, to suggest an even more staggering ethical and legal implication of biotechnology. Drawing upon the theory of evolution, Professor Coletta discusses how our species' sense of ethics, and our rules of law, might themselves be the product of biological evolution. If so, does biotechnology create the prospect that humans could reengineer their sense of right and wrong, and, in turn, mean that, instead of the law controlling genetic development, genetic development will control the law?

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The next article is from my colleague, Kojo Yelpaala. Professor Yelpaala's scholarship over the years has challenged the conventional wisdom concerning the impact of various laws—such as investment rules, tax incentives, contractual and corporate structures and, of pertinence here, treatment of intellectual property—on economic development. In his article, Professor Yelpaala examines the intellectual property issues raised by biotechnology development. Biotechnology has set off a debate over the extent to which companies can claim exclusive intellectual property rights in biological research results. The economic importance of this debate became even more evident when not so long ago, the prices of biotechnology company stocks plummeted in reaction to statements by President Clinton and English Prime Minister Blair, which some interpreted as calling into question the ability of companies to exercise exclusive rights over the results of mapping the human genome. Professor Yelpaala's article, however, has gone beyond the narrow technical intellectual property issues raised by biotechnology. Instead, Professor Yelpaala argues that deciding upon an appropriate intellectual property regime for biotechnology requires answering fundamental questions as to the purposes and nature of property.

The third article is from my colleagues Julie Davies and Larry Levine. Professors Davies and Levine have written books and articles in the area of tort law, and, accordingly, their article looks at the tort law issues raised by biotechnology. Much of tort law has developed in reaction (often a delayed reaction) to technological developments. For example, both common law tort doctrine and alternative statutory compensation regimes have developed to deal with injuries to workers due to the new manufacturing technologies introduced in the industrial revolution, the deaths and injuries resulting from the advent of the automobile, and harms to consumers resulting from the mass production and distribution of potentially dangerous products. Additionally, Professors Davies and Levine consider the challenges posed to the existing tort system by biotechnologically created harms. They look at whether biotechnology poses issues of sufficient complexity and novelty to merit special legal treatment, such as an overall exemption from tort liability or a refusal to apply strict liability in the biotechnology context. Professors Davies and Levine discuss how injuries resulting from biotechnology may arise and try to anticipate how courts will deal with these cases.

My article considers some of the business organization issues facing the biotechnology industry. My interest in the business organization issues facing this industry stems from having made a biotechnology company the focus of the problem set found in my widely used casebook on Business Planning. From a business organization standpoint, what strikes one about the biotechnology industry is the sheer magnitude of the dollars involved, both in terms of funding research and development, and in terms of potential liability if things go awry. I shall look at a couple of the implications for business organization issues which these huge dollar sums entail.

The final article is by Judith Cregan. Ms. Cregan is a recent graduate of the McGeorge School of Law, who worked in the biotechnology arena prior to attending law school. Ms. Cregan's article examines the current regulatory structure for experimental gene therapy. This is a particularly timely topic in light of the recent unfortunate death of a young man who was receiving such treatment. Ms. Cregan highlights some of the problems with the current regulatory regime, and proposes several specific reforms to the current regulatory structure in order to enable society to better realize the promise of gene therapy.

As I said at the outset, the purpose of these papers is to answer two questions: Why Biotechnology? Why McGeorge? The papers explicitly speak to the first question. In putting together this project, I asked my colleagues to prepare articles which identify the legal issues facing the biotechnology industry in their fields of expertise. The result, as I hope the reader will agree, is to make a persuasive case that the legal issues created by biotechnology call for focused and sustained attention. I hope the reader also will agree that the quality of these articles, and the expertise my colleagues bring to these subjects, provide an implicit answer to the second question. There is an additional answer, however, as to why this institution should provide such focused and sustained attention on the legal issues facing biotechnology. The Sacramento area is one of the birthplaces of the biotechnology industry, and Northern California remains the locus of much of the industry. Hence, it is in our interest, and our responsibility, to study the legal issues facing this industry.

This just leaves one question: Where do we intend to go from here? These articles introduce the legal issues facing the biotechnology industry; they do not provide a comprehensive exploration of these issues from different viewpoints. That will be the goal of future symposia, which will devote their attention to looking at each of these subject areas, one at a time. My colleague, Steven McCaffrey, has already started this process. Professor McCaffrey's area of expertise is international law in general, and international environmental law in particular, having served on the United Nations' International Law Commission, and been the Commission's rapporteur for its work on the non-navigational uses of international water courses. In response to my request for an article on the international law issues facing biotechnology—which has been the subject of a recent international treaty—Professor McCaffrey went one better. He organized a symposium on this topic, which took place at McGeorge last spring.

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