Law and Biotechnology

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Cases and Materials

Victoria Sutton
Robert H. Bean Professor of Law
Texas Tech University
School of Law

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Foreword

As you embark on this interdisciplinary and multidisciplinary study of Law and Biotechnology, my hope is that this book will assist you in examining the immense impact that biotechnology and law has on our society. It will undoubtedly affect you in your practice of law, in some way, during the course of your career; if not directly in many areas of practice which include not only intellectual property, but international trade, criminal law, agricultural law, business law and environmental law, to name but a few areas.

The practice of law is increasingly requiring a level of science literacy that will be required of anyone who is graduating from law school, today. This is particularly true in the field of biotechnology, which is a scientific field enjoying an explosion in growth and understanding, much like the scientific field of physics in the first half of the last century. As law develops to shape the way that our society regulates behaviors, it must quickly respond to the new and exciting possibilities of biotechnology. The opportunities to provide legal expertise and guidance in this field are great; and it is with an understanding of the science, scientists and engineers as well as the regulatory mechanisms that we can best optimize these opportunities for the benefit of society and future generations.

As this book goes to press, it is with the realization that new discoveries and new applications of the law in biotechnology will be developing as the ink is drying. But the foundations that are set forth in this text, provide you with the intellectual toolkit that should serve you well as you enter what will certainly be an exciting time in our history for judges, practicing lawyers and legal scholars in the field of Law and Biotechnology.

Victoria Sutton
Lubbock, TX

March 2007

Preface

This book provides a systematic look at law, policy, science and technology of biotechnology in the context of the traditional fields of law and practice. Chapter One begins with an introduction to the categories of biotechnologies as a way of understanding the scope of applications that are possible, raising awareness of law and policy issues. In this chapter, biotechnology is defined and the historical relationship between law and biotechnology is examined beginning with the earliest biotechnologies of food processing, animal breeding and winemaking and continuing up to the biotechnology explosion beginning in the 1980s. The chapter introduces the definitions for genomics, proteonomics, bionanotechnology and bioinformatics. An introduction to the scientific method and the sciences of biotechnology is explained at this early point in the book as a foundation to understanding. The chapter concludes by an introduction to the issue of whether life can be patented through examination of the case, *Diamond v. Chakrabarty.*

Chapter Two addresses issues of distributions of power in the regulation of biotechnology and a discussion of the earliest regulatory approaches in the development of the federal regulatory framework. The scope of authority for the regulation of biotechnology is examined through the litigation concerning genetically engineered foods with the Food and Drug Administration and Environmental Protection Agency, including administrative decisionmaking and Constitutional issues. The regulation of genetically modified organisms including plants and the environmental impact is examined through the litigation with the U.S. Environmental Protection Agency and Department of Agriculture and the National Institutes of Health. The work of biopharming is examined in the context of litigation with the U.S. Department of Agriculture. Completing this chapter is an examination of federal legislation which has been introduced concerning various policy issues of biotechnology, and the efforts of states to regulation biotechnology.

Chapter Three turns to the private sector and corporate activities in biotechnology, the unique features of biotechnology patents as well as the new professions which are developing around the emergence of biotechnologies in our lives. Unique problems for biotechnology of patent ownership, enforcement and infringement are examined in *Monsanto v. Schmeiser*.

Chapter Four, addresses some of the unique law and policy issues of biotechnology in human health, medical care and medical information. The constitutional right to privacy, adoption right to know, experimental and treatment decisions, informed consent and predisposition to disease as it relates to health insurance are among the ideas discussed in this chapter.

Chapter Five addresses international laws in biotechnology which affect the United States in the context of patenting, biological diversity, trade, security, biodefense, human rights, indigenous peoples, bioprospecting and biopiracy. Discussions of the

FAO International Treaty on Plant Genetic Resources for Food and Agriculture, the WTO Agreement on Trade-related Aspects of Intellectual Property Rights, the WIPO conventions and treaties, the International Convention for the Protection of New Varieties of Plants, the United Nations Convention on the Law of the Sea, the Convention on International Trade in Endangered Species of Wild Fauna and Flora, the Antarctic Treaty and the Human Genome Project are discussed in the context of biotechnologies.

Chapter Six tackles the broad area of ethics, religion and biotechnology by first examining religion and biotechnology and then ethics and biotechnology. Work of the National Bioethics Advisory Committee is reviewed as it explored the religious views of stem cell research and cloning among religious denominations. The family perspective is also reviewed from the question of who is family? Legal vs. biological definitions of family, reproductive technologies, eugenics, stem cell research and cloning are considered in this broad field of ethics, law and biotechnologies. The chapter concludes with consideration of the ethics of contamination of indigenous crops with genetically modified crops.

Chapter Seven considers criminal law and the role biotechnology has played in a range of legal contexts. Federal criminal statutes both new and old are explored in their application to biotechnologies. The use of DNA, and mitochondrial DNA in criminal law, the changing "expectation of privacy" with the use of new biotechnologies, human behavioral genetics and criminal predisposition are among the topics examined in this chapter. This is followed with cases which raise issues of ineffective representation by counsel where knowledge of biotechnology proves essential. A newly characterized crime of biopiracy is a final thought for the future in this chapter.

Chapter Eight reviews the foundation cases in scientific evidence and builds on these to introduce DNA testing and evidence. The emerging study of historical forensics examines some recent cases of interest to historians with legal consequences and raises new ethical issues for its practice.

Chapter Nine is introduced with the landmark case, of *Moore v. Regents of University of California* addressing the issue of ownership with human tissues. Special property protection problems of biotechnology are examined including the ownership of human organs, fertilized human eggs, sperm and umbilical cord blood storage banks.

Chapter Ten considers the application of traditional tort law to the new biotechnologies in the categories of intentional and unintentional torts, specifically trespass to land, conversion, private nuisance, public nuisance and negligence. Other torts are newly emerging areas which may utilize biotechnologies including wrongful birth and wrongful life, medical malpractice and products liability and strict liability.

The book necessarily concludes with a look at the future of law and biotechnology in the last Chapter Eleven.

Four appendices have been created specifically for the use of this book to assist in clarifying terms in biotechnology and general principles in the major scientific disciplines which are used to develop biotechnologies: cell biology, molecular biology, a primer on DNA and a glossary.

About the Author

Victoria Sutton, M.P.A., Ph.D., J.D.
Robert H. Professor of Law, Texas Tech University

Victoria Sutton is the Director of the Center for Biodefense, Law and Public Policy, Director of the Law and Science Certificate Program and the Robert H. Bean Professor of Law at Texas Tech University.

She holds a Ph.D. in Environmental Sciences from The University of Texas at Dallas; a J.D. from American University, *magna cum laude;* and a Master's Degree in Public Administration (MPA), from Old Dominion University, who awarded her the Distinguished Alumni Award in 2005. She also has two Bachelor of Science degrees in Zoology and Animal Science, *cum laude*, from North Carolina State University.

Before coming to Texas Tech, she was Assistant Director in the Bush Administration from 1990 to1993, in the Office of Science and Technology Policy in the White House Science Office, where she worked on national energy and environmental policy. Prior to that, she worked in the U.S. Environmental Protection Agency as a Special Assistant in Policy, Planning and Evaluation and EPA Liaison to the Office of Science and Technology Policy of the White House. Following the Bush Administration, she was appointed as the Executive Director of the Ronald Reagan Institute of Emergency Medicine in Washington, DC.

Since coming to Texas Tech, Dr. Sutton was a Visiting Lecturer at Yale Law School in 2004 and also served in the President George W. Bush Administration as Chief Counsel of the Research and Innovative Technology Administration, U.S. Department of Transportation from 2005 to 2007.

Dr. Sutton is a member of the District of Columbia Bar, U.S. Federal Circuit Bar and the U.S. Supreme Court Bar. She has served as a consultant to a number of federal agencies in the area of biodefense, and is a frequent speaker for audiences of lawyers as well as scientists.

Her awards include receiving the Distinguished Alumni Award from Old Dominion University. She received the Texas Tech University Book Award in 2003 for *Law and Science: Cases and Materials*; and the Law School Distinguished Research Award in 2002, 2003 and 2005. She is also the author of *Law and Bioterrorism*, a first in the field, released January 2003.

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Appendix 4. Glossary

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