Summary of Course

This seminar course will address the dynamic biotechnology industry and the law affecting it. The course will begin with an overview of the history and trends within the industry considering biotechnologic products and methods in the production of food, in pesticides and in the drugs and biologics used in medicine. Part II of the course will consider the regulatory framework applicable to these new products and how it has been modified to address the special issues presented by use of biotechnologic methods, focusing on FDA, EPA and USDA regulations. Part III will turn to protection of and property rights in new biotechnology products including ownership and patentability. The course will conclude with study of the risks and liability faced by the biotechnology, especially in the context of products liability and toxic torts. During the course, the student will research and write a four part case study on a biotechnologic product assigned by the professor.

Required Texts

The Course Materials include several recent cases, articles, excerpts from books and other texts, and legislative/regulatory materials. The Course Materials will be available in two sets. Set I will include materials for the first five weeks of class and Set II will cover the last four weeks of class. In addition to the assigned reading materials, there is a listing of additional readings available in the library that may prove useful for researching the cases studies.

Class Participation

The course will be conducted in lecture\discussion format. Active participation by students is strongly encouraged.

Course Grade

The course grade will be based upon a four part case study researching the development and use of a biotechnology product. The class sessions will serve to provide the student with a general overview of the law to serve as the underpinning for the more detailed and product-oriented research necessary for the case study. Part I of the case study (5-10 pages) will describe the biotechnologic and scientific advances
leading up to the development of the product, the uses for the product, and public policy and ethical concerns (if any) raised during development. Part II of the study (10-12 pages) will trace the product’s journey through the regulatory maze and what specific regulations had to be complied to bring the product to market. Part III of the study (10-12 pages) should focus on the intellectual property protections available to and chosen by the manufacturer or inventor of the product. Finally, part IV of the study (10-12 pages) will consider the potential liability associated with the product and means by which the manufacturer might protect against that liability. Due dates for each part of the case study will be as follows: Part I, April 14; Part II, May 5; Part III, May 19; Part IV, June 3.

Course Outline

I. Biotechnology: History and Trends
   A. Evolution of a 20th Century Industry
      1. Agricultural and Food Products
      2. Pesticides and Herbicides
      3. Drugs, Biologics and Medical Products
   B. Commercial Expansion and Economic Growth
   C. Public Policy and Ethical Issues

Week of Mar 31

Reading Assignment:
Principles of Biotechnology

Additional Readings & Materials:

I. Biotechnology: History and Trends

A. Evolution of a 20th Century Industry
   1. Agricultural and Food Products
   2. Pesticides and Herbicides
   3. Drugs, Biologics and Medical Products

B. Commercial Expansion and Economic Growth

C. Public Policy and Ethical Issues

Week of April 7

Reading Assignment:


57 Fed. Reg 9753, Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment (Feb. 27, 1992)


Strachan Donnelley, Exploring Ethical landscapes; The Brave New World of Animal Biotechnology, 24 Hastings Center Report S3 (Jan 1994)

Marjorie Sun, Administration Divided Over OECD Biotech Plan, 229 Science 842 (1985)
II. Regulation of Biotechnology - Accessing the Market

A. Food and Drug Administration (FDA)

**Week of April 14**

*Reading Assignment:*


Community Nutrition Institute v. Novitch, 773 F. 2d 1356 (1985)


*Additional Readings & Materials:*


B. United States Department of Agriculture

**Week of April 21**

*Reading Assignment:*


Cordes v. Madigan, 1992 U.S.Dist LEXIS 6250

Barusch v. Calvo, 685 F. 2d 1199 (1982)

*Additional Readings & Materials:*

Alan Goldhammer, *The Regulation of Agricultural Biotechnology: An Industrial Perspective*, 48 Food & Drug L. J.

60 Fed. Reg. 43567, Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organisms

59 Fed. Reg. 45526, Microbial Products of Biotechnology; Proposed Regulation Under the Toxic Substances Control Act (Sept. 1 1994)
C. Environmental Protection Authority

**Week of April 28**

*Reading Assignment:*

Henry Miller, *A Need to Reinvent Biotechnology Regulation at the EPA*, 266 Science 1815 (1994)

Nat=I Coalition Against the Misuse of Pesticides v. Thomas, 809 F. 2d 875 (1987)


*Additional Readings & Materials:*


III. Protecting Biotechnology Products

A. Property Rights
B. Technology Transfer
C. Patents

Week of May 5

Reading Assignment:

Moore v. Regents of the University of California, 793 P.2d 479 (1990).


Margaret Swain & Randy Marusyk, An Alternative to Property Rights in Human Tissue, Hastings Center Report, Sept.


Additional Readings & Materials:


David Blumenthal et al., University-Industry Research Relationships in Biotechnology:
Implications for the University, 232 Science 1361 (1986).


Week of May 12

Reading Assignment:


Additional Readings & Materials:


Asgrow v. Winterboer, 982 F.2d 486 (Fed Cir. 1994).
Fiers v. Sugaro, 984 F.2d 1164 (Fed Cir. 1993).
Hybritech Inc. C. Monoclonal Antibodies Inc.  802 F.2d 1367 (Fed Cir. 1986).
Hormone Research Foundation v. Genetech, Inc., 904 F.2d 1338.
Scripps Clinic v. Genentech, 927 F.2d 1565.
IV. Liability Risks

A. Products Liability

B. Toxic Torts

**Week of May 19**

*Reading Assignment:*


Davis v. Wyeth Laboratories, 399 F. Supp. 1023 (9th Cir. 1968).


*Additional Readings & Materials:*


IV. Liability Risks

A. Products Liability

B. Toxic Torts

Week of May 26

Reading Assignment:


Additional Readings & Materials:


List of Products:

Intron-A
Protropin
Neupogen
Epogen
Leukine
Avonex
Betaseron
Activase
Flavr Savr Tomato
Posilac (rBST)
Ceredase\Cerezyme
Pulmozyme
RespiGam
Chymogen\ChyMax
New Leaf Insect Protected Potato
Humulin\Novolin
Recombivax
Orthoclone OKT3
Bollgard Insect Protected Cotton
CIBA Maximizer Hybrid Corn