Course Materials: You purchase a course packet at KING KOPY (corner of Lindsay Street and Jenkins Avenue). The course packet will cost $30. The course packet consists of two parts:

Part One – Introductory Chapter: The Basic Science of Biotechnology

You should use a three-ring binder for the course packet.

When you purchase the course packet, you will pay $30 for the entire set of materials. But the CHEN & KERSHEN materials end at p. 363 presently. There will be approximately 200 additional pages. KING KOPY will also photocopy these additional pages but I will get them and deliver them to you during class time. There will NOT be any additional charge for these additional pages.

The first week uses Part One of the packet. The reading assignments for the first three days of class are part of Part One. Please be prepared for the first three classes in accordance with the assignments in Part One of the packet.

Class Days: The course meets on Monday, Tuesday, Wednesday from 10 a.m. to 11 a.m. There is the need for one make-up class already in the first week of school. We will discuss this make-up class on the first day of class.

Reasonable Accommodation: The University of Oklahoma is committed to providing reasonable accommodation for all students with disabilities. Students with disabilities who require accommodations in this course are requested to speak with the professor as early in the semester as possible. Students with disabilities must be registered with the Office of Disability Services prior to receiving accommodations in this course. The Office of Disability Services is located in Goddard Health Center, Suite 166, phone 405/325-3852 or TDD only 405/325-4173.

Grading: You will have three take-home exams during the course of the semester. I have included these in the syllabus in order to give you notice as to when these exams/papers will occur. There is no comprehensive final examination in this course.

Class participation: I expect that you will read the assigned material for each week. I expect that you will be prepared to discuss the assigned material in class each week. I expect you to attend class each week. If you must be absent, the first three absences are excused but any absence above three must have an explanation acceptable to me to gain an excuse. Above two absences, unless excused, the professor has discretion to reduce your final grade.
We will attempt to follow the syllabus closely although as the course progresses it may be necessary to rearrange the amount of time devoted to particular topics.

**Class Assignments**

**PART I OF AGRICULTURAL BIOTECHNOLOGY: INTRODUCTION TO BASIC SCIENCE AND BASIC AGRICULTURAL POLICY**

**CLASSES ONE, TWO AND THREE**

The reading assignment for the three classes of Week One are clearly set forth in the Table of Contents of the Introductory Chapter: The Basic Science of Biotechnology.

For the first three class periods, we will gain an understanding of the basic science involved in biotechnology. By the end of this week, you should have acquired a basic understanding of the science of biotechnology and issues for social policy.

**CLASS FOUR**

CHEN & KERSHEN Ch. I. *Introduction to Agricultural Law* – Sec. A – pp. 1-32

**CLASS FIVE**

CHEN & KERSHEN Ch. I *Introduction to Agricultural Law* – Section B – 32-53

Classes 4 & 5 introduce basic agricultural policy issues. What is agriculture? Should agriculture be treated differently by regulatory agencies? What is the meaning and impact of the concept of the "industrialization" of agriculture? These two classes are meant to give us a good introduction to two fundamental themes in the course.

**PART II OF AGRICULTURAL BIOTECHNOLOGY: INTELLECTUAL PROPERTY ISSUES IN AGRICULTURE**

**CLASS SIX**

CHEN & KERSHEN Ch. II. *Biotechnology* -- Section A -- pp. 53-73

This class is meant to give us a good introduction into agricultural intellectual property issues, public versus private agricultural research, and the public policies about agricultural intellectual property.

**CLASS SEVEN**

CHEN & KERSHEN Ch. II. *Biotechnology* -- Section B pp. 73-98

In Section B, we begin to study the first federal law providing intellectual property rights relating to agricultural "discoveries and inventions." The Plant Patent Act of 1930

**CLASS EIGHT**

CHEN & KERSHEN Ch. II *Biotechnology* -- Section C subparts 1 & 2 -- pp. 98-115

**CLASS NINE**
Classes 8 & 9 address the second federal law providing intellectual property rights relating to agricultural "discoveries and inventions." The Plant Variety Protection Act of 1970 (amended 1994). This law shows us a change in agricultural technology and how the federal law responded to that change.

CLASS TEN

   CHEN & KERSHEN Ch. II Biotechnology -- Section D subparts 1, 2 -- pp. 148-166

This class brings us into the era of present-day biotechnology and the debates arising about patents on genetic discoveries and inventions under the regular patent law. The Patent Act (utility patents.)

CLASS ELEVEN

   CHEN & KERSHEN Ch. II Biotechnology – Section D subpart 3 – pp. 166-175
   *Diamond v Chakrabarty –*

CLASS TWELVE

   CHEN & KERSHEN Ch. II Biotechnology -- Section D subparts 4 & 5 -- pp. 175-189

This class continues our discussion of present-day technology and the debates arising about genetic patents under the regular patent law. By the end of this class we should have a good feel for all the patent laws applicable to agricultural "inventions." Moreover, we should have a good understanding for the policy debates that exist about these patent laws as applied to agricultural "inventions."

CLASS THIRTEEN

   CHEN & KERSHEN Ch. II Biotechnology -- Section E subparts 1, 2, 3 -- pp. 189-213

CLASS FOURTEEN

   CHEN & KERSHEN Ch. II Biotechnology – Section E subpart 4 – pp. 213-229

Classes 13 & 14 build on what we have learned in the previous classes so that we can intelligently address proposed patent reforms -- why they are being made, what these reforms mean. Subsection E allows us to address these patent reform proposals.

CLASS FIFTEEN

   CHEN & KERSHEN Ch. II Biotechnology -- Section F subparts 1, -- pp. 229-238

CLASS SIXTEEN

   CHEN & KERSHEN Ch. II Biotechnology – Section F subpart 2– pp. 238-242

Classes 15 & 16 focus on infringement issues by looking at a Canadian case and by looking at an American case.

CLASS SEVENTEEN
Classes 17 & 18 raises the following issue. If agricultural inventors were not allowed to use patents, so what? Inventors have alternative ways to protect their “inventions.” We can compare and contrast these alternative forms of protection with the protections provided by the various patent laws.

**FIRST TAKE-HOME EXAMINATION:** Distributed at the end of Class 18 to be returned by the following Saturday to Room 3025 or by e-mail by 4:00 p.m. Class 18 should be February 23, 2005 (a Wednesday).

The syllabus will continue when I have completed Chapter Three and Chapter Four on *International Issues in Agricultural Biotechnology*. I hope to have these materials completed and the syllabus for the course completed by early February 2005.

**The second take home examination** is scheduled at the end of Class 30 on Wednesday, March 30, 2005.

**The third take home examination** is scheduled at the end of Class 42 (the end of the course) on Wednesday, April 27.
PART III OF AGRICULTURAL BIOTECHNOLOGY – REGULATORY STRUCTURES

CLASS NINETEEN
  KERSHEN & CHEN Ch. III Administrative Regulations – Section A, subparts 1 & 2 pp. 278-304
  The materials for today’s reading assignment address food safety regulation using the first bioengineered food, a genetically altered tomato, as a case study. In addition, we will read popular literature about food safety generally and the tomato specifically. These materials set the background for understanding food safety.

CLASS TWENTY
  Ch. III Administrative Regulations – Section A, subpart 2 pp. 304-320
  The materials for today shift the focus from food safety to issues about labeling which are related to consumer information and consumer preferences about foods. From these materials, you should be able to articulate and understand the policy position of the Food and Drug Administration about labeling.

CLASS TWENTY-ONE
  Ch. III Administrative Regulations – Section A, subpart 3A pp. 320-338
  The materials for this class focus on the USDA regulatory authority for agricultural biotechnology.

CLASS TWENTY-TWO
  Ch. III Administrative Regulations – Section A, subpart 3B, pp. 338-363
  The materials for this class focus on the Environmental Protection Agency regulatory authority for agricultural biotechnology.

CLASS TWENTY-THREE
  Ch. III Administrative Regulations – Section A, subpart 3C, pp. 363-369
  The materials for this class focus on FDA regulatory authority for agricultural biotechnology. This class adds to the information and knowledge gained in Classes 19 & 20. When you have finished reading the materials for Classes 19-23 and heard the class discussion, you should have a good understanding of the regulatory system for GMOs in the United States.

CLASS TWENTY-FOUR
  Ch. III Administrative Regulations – Section A, subpart 3D, pp. 369-386
  The materials assigned for today introduce European regulation relating to GMOs. The Council Directive 2001/18EEC should be compared and contrasted to the regulations of the USDA and the EPA.

CLASS TWENTY-FIVE
**Ch. III Administrative Regulations** – Section A, subpart 3D, pp. 386-401

The materials for today’s reading about European food safety regulation relating to GMOs should be compared and contrasted to the FDA policy and regulation of bioengineered food in the United States. Reg. (EC) 1829/2003

**CLASS TWENTY-SIX**

**Ch. III Administrative Regulations** – Section A, subpart 3D, pp. 401-421

The materials for today focus on the issue of coexistence. How can various types of agriculture coexist. Reg. (EC) 1820/2003 and the German Genetic Modification Act serve as the primary readings.

**CLASS TWENTY-SEVEN**

**Ch. III Administrative Regulations**– Section I, subpart 4, pp. 421-444

We begin a case study of the approval of rBST. We look at the regulatory process.

**CLASS TWENTY-EIGHT**

**Ch. III. Administrative Regulations** – Section I, subpart 4, pp. 444-456

We continue our study of rBST and look at the political debates.

**CLASS TWENTY-NINE**

**Ch. III. Administrative Regulations** – Section I, subpart 4, pp. 456-475

We focus on several cases arising from the approval of rBST.

**CLASS THIRTY**

No new reading assignment. A catch-up class to allow us to finish previously assigned readings.

By the end of Classes 27, 28, 29, & 30, you should have a solid understanding not only of a particular case study — rBST — but of the debates that swirl around agricultural biotechnology domestically and in Europe. These same issues are reprised in the international area, with a few new twists, as will be seen in the last Part of the course.

**SECOND TAKE-HOME EXAMINATION: Distributed at the end of Class 30; to be returned on the following Saturday to Room 3025 or be e-mail by 4:00 p.m. Class 30 should be on Wednesday March 30, 2005.**
PART IV: INTERNATIONAL TREATIES AND AGENCIES AFFECTING AGRICULTURAL BIOTECHNOLOGY

CLASS THIRTY-ONE

Ch. III Biotechnology – Section A, subpart 1, pp. 479-495

The materials assigned for today’s reading provide the basic international legal documents relating to intellectual property rights in the international fora – the UPOV 1990 and WTO.

CLASS THIRTY-TWO

Ch. III Biotechnology – Section A subpart 2, pp 495-512

The reading for today is the European Union patent decision that is comparable to the United States Supreme Court decision in Diamond v. Chakrabarty

CLASS THIRTY-THREE

Ch. III Biotechnology – Section B subpart 1 pp. 512-535

Today’s reading shifts focus from intellectual property to access to genetic resources. The readings present the basic international documents and concepts relating to access to genetic resources.

CLASS THIRTY-FOUR

Ch. III Biotechnology – Section B subpart 2, pp. 535-547

The reading provides the present resolution of access to genetic resources at the international level.

CLASS THIRTY-FIVE

Ch. III Biotechnology – Section B subpart 3, pp. 548-583

Domestic legal and policy implementations of the international conventions on access to genetic resources and an evaluation of these domestic and policy implementation

CLASS THIRTY-SIX

Ch. III Biotechnology – Section B subpart 4, pp. 583-606

The reading for today provide a broader perspective and evaluation of the legal and policy implementations concerning access to genetic resources that we discussed on the previous classes.

CLASS THIRTY-SEVEN

Ch. III Biotechnology – Section B, subpart 5, pp. 606-618

Issues about access to genetic resources also exist in the domestic law of the United States. The readings for today focus on the two cases that have presented the issue of access to genetic resources under United States law.
CLASS THIRTY-EIGHT

Ch. III Biotechnology – Section C pp. 618-627

The focus is on a very practical issue – the transfer of technology covered by intellectual property rights and involving genetic resources from a developed nation to a developing nation. We use the example of Golden Rice™ as the case study for the practical questions involved in technology transfer.

CLASS THIRTY-NINE

Ch. III Biotechnology – Section D subpart 1, pp. 627-649

Focus on the Cartagena Protocol on Biosafety which regulates international trade in GMOs. The Cartagena Protocol is comparable to USDA and EPA regulation in the United States and EU Directive 2001/18/EC.

CLASS FORTY

Ch. III Biotechnology – Section D subpart 1, pp. 649-658

Focus on policy discussion of the Cartagena Protocol on Biosafety

CLASS FORTY-ONE

Ch. III Biotechnology – Section D subpart 2, pp. 658-668

Focus on Codex Alimentarius and international food safety regulations. We work to understand the model of regulation and its implications. We work to see the interconnection between the food safety regulations and other international regulations.

CLASS FORTY-TWO

Ch. III Biotechnology – Section D subpart 2.A and 2.B, pp. 668-677

Focus on food safety risk assessment at the international level through Codex Alimentarius.

The materials discussed in Classes 41 & 42 are comparable to the US-FDA materials and to EU Regulation No. 258/97 on Novel Foods.

Students also evaluate the course.

THIRD TAKE-HOME EXAMINATION. Distributed at the end of Class 42 to be returned by the following Saturday to Room 3025 or by e-mail by 4:00 p.m. Class 42 will be April 27 (Wednesday)