# UMBC UGC New Course Request: BTEC 300: Biotechnology Survey: Legal, Ethical, Regulatory & Biosafety Issues

Date Submitted: 04/04/2014 (revised 10-6-15) Proposed Effective Date: Fall 2015

| | Name | Email | Phone | Dept |
|---|---|---|---|---|
| Dept Chair or UPD | William R. LaCourse | lacourse@umbc.edu | X55827 | CNMS |
| Other Contact | Mauricio Bustos | bustos@umbc.edu | X52769 | BIOL |

**COURSE INFORMATION:**

| | |
|---|---|
| Course Number(s) | BTEC 300 |
| Formal Title | **Biotechnology Survey: Legal, Ethical, Regulatory & Biosafety Issues** |
| Transcript Title (≤30c) | Legal Ethic Regulatory Issues |
| Recommended Course Preparation | |
| Prerequisite | See below |
| Credits | 3 |
| Repeatable? | ☐ Yes ☒ No |
| Max. Total Credits | 3 |
| Grading Method(s) | ☒ Reg (A-F) ☐ Audit ☐ Pass-Fail |

**PROPOSED CATALOG DESCRIPTION (**no longer than 75 words**):**

This course will raise awareness on a range of non-technical topics that frame the field of translational medicine and the biotechnology industry. Meetings will cover topics on the ethics of biotechnology (e.g. genomic mining and manipulation, synthetic life), legal decisions that affect what products can be patented by the biotechnology industry, and regulatory trends in the US and abroad.

**RATIONALE FOR NEW COURSE:**

This course will be part of the upper level (years 3 and 4) of a joint program in Translational Life Science Technology (2+2 TLST) created and run by UMBC in partnership with Montgomery College. The course will introduce students entering the upper level of the Translational Life Science Technology program to important legal, ethical, regulatory and biosafety topics for the fields of biotechnology and translational medicine. The Translational Life Science Technology (2+2 TLST) is being managed through the College of Natural and Mathematical Sciences at UMBC due to the interdepartmental, intercollegiate, and inter institutional nature of the joint program, which is being developed by a faculty committee involving Dr. Mauricio Bustos, Dr. Charles Bieberich, and Dr. Mariajose Castellanos.

Prerequisites (all must be passed with a "C" or better): CHEM 101, PHYS 111, BIOL 142, BIOL 302.

**ATTACH COURSE OUTLINE (mandatory):**

**OUTLINE -** BTEC 300: Biotechnology Survey: Legal, Ethical, Regulatory & Biosafety Issues

## Summary

This course will meet once weekly for three hours on Tuesday or Wednesday. The lectures will be delivered by distinguished guest lecturers from academia, the private sector, or government agencies. The first half of the class will be devoted to a seminar-styled lecture. The second half will comprise an active learning discussion moderated by the course instructor and the guest lecturers. The course instructor (a UMBC faculty member) will be responsible for the course organization and administration, and will assign and grade all the work submitted by the students. Before each class session, students will be assigned readings selected from materials relevant to each topic and from the bibliography provided by the guest lecturers. The course grade will be based on student participation, two midterm tests designed to evaluate comprehension of course topics, and a written group assignment.

## Syllabus

### Learning objectives

At the end of the semester, students should have:

a. Acquired the basic concepts and vocabulary pertaining to legal, ethical and regulatory issues important for translational medicine and the biotechnology industry.
b. Gained an understanding of the main challenges faced by the biotechnology industry in the 21st century, and how the industry interacts with the legal system, the ethics community, the regulatory agencies, and the public.
c. Grasped the considerable power that the courts, the ethics community and government agencies can exert directly and indirectly over the course of the biotechnology industry and medicine.
d. Attained competency on how to access resources to address relevant legal, ethical and regulatory issues.

### Textbook and other didactic materials

No textbooks will be used in this course. Appropriate reading materials will be compiled from the scientific literature, from legal briefs, regulatory laws and published essays on ethics and law. A list of bibliographic references is shown at the end of this outline.

***Calendar (weekly)***

| Week | | | |
|---|---|---|---|
| 1 | | Introduction | |
| 2 | Part I: Ethical issues | Invited lecture 1 | On holding intellectual property rights on living organisms and genomes |
| 3 | | Invited lecture 2 | On cloning live animals, tissues, and cells (e.g. stem cells) |
| 4 | | Invited lecture 3 | On engineering new and modified life forms |
| 5 | | Review | Group learning activity and review |
| | | Midterm I | Covers all the materials seen in the ethical issues segment (first writing assignment due) |
| 6 | Part II: Legal issues | Invited lecture 1 | On US and international laws that govern intellectual property |
| 7 | | Invited lecture 2 | On civil and criminal liability laws that apply to biotechnology |
| 8 | | Invited lecture 3 | On environmental and safety laws |
| 9 | | Review | Group learning activity and review |
| | | Midterm II | Covers all the materials seen in the legal issues segment (second writing assignment due) |
| 10 | Part III: Regulatory issues | Invited lecture 1 | On federal and State regulatory agencies: FDA, EPA, etc |
| 11 | | Invited lecture 2 | On new product approval procedures, e.g. clinical trials |
| 12 | | Invited lecture 3 | On industry best practices, certification, etc. |
| 13 | | Review | Group learning activity and review |
| 14 | | Final exam | Covers all the materials seen in the regulatory issues segment (third writing assignment due) |

**Example session**
Below is brief description of the type of invited lecture and activities that will be part of this course.
" Invited lecture 1: On holding intellectual property rights on living organisms and genomes"

**Invited speaker/expert:** Guido Galvez, The Johns Hopkins University and University of Maryland Francis King Carey School of Law.

**Speaker's biographical sketch:** B.S. 1995, University of Maryland Baltimore County; M.S. 1997, University of Maryland Baltimore County; J.D. 2001, Catholic University of America

**Expertise:** Mr. Galvez has been in-house IP counsel at The Johns Hopkins University since 2010. Prior to joining JHU, Mr. Galvez practiced in large law firms in Washington, D.C. He practices in all areas of intellectual property law, specializing in biotechnology and pharmaceutical patent counseling, and technology transfer

In this session Mr Galvez will outline the three most ethically controversial issues related to the patenting of genes, namely, treating life as a commodity, the appropriateness of patenting naturally occurring living organisms, and undermining the dignity of life and people. Arguments against government's granting of intellectual property rights will be raised and contrasted with the benefit of patenting, mainly seen as an incentive to private innovation and commercialization of biotechnology products and services that save lives, raise the standard of living, and employ people in high paying jobs.

"The patenting of genes is a controversial issue in terms of bioethics. There are three main concerns voiced about genetic patenting. First, some believe it is unethical to patent genetic material because it treats life as a commodity. Second, some say that living materials occur naturally, and therefore cannot be patented.[9] Finally, there is the fear that allowing patents on genetic material will undermine the dignity of people and other animals by subjecting their genes to ownership by other people.[10] .. The ethics of using patents to increase profits are also debated. A typical argument in favor of biotech patents is that they enable companies to earn money that the companies in turn invest in further research. Without these patents, some worry that companies would no longer have the resources or motives to perform competitive, viable biotech research.[9]"

Abstracted from Wikipedia, http://en.wikipedia.org/wiki/Biological_patent

Following Mr Galvez's lecture, the floor will be open to a Q&A with the speaker, and a free debate on the ethics of patenting life, genes, and genomes. After the debate, each student group will present an oral summary of the lecture, and will share their insights with the rest of the class.

**Sample Bibliography**
Berkowitz, A, and Kevles, DJ. 2002 Patenting human genes: the advent of ethics in the political economy of patent law. In: Magnus, David; Caplan, Arthur; McGee, Glenn, eds. Who Owns Life? Amherst, NY: Prometheus Books; pp. 75-97.

Laurie, G. 2004 Patenting stem cells of human origin. AHRC Research Centre for Studies in Intellectual Property and Technology Law.

Beeson, D. and Lippman, A. 2006 Egg harvesting for stem cell research: medical risks and ethical problems Reproductive BioMedicine Online.

**Writing assignments**

In order to comply with current Writing Intensive Program guidelines, students enrolled in this course will be required to submit three 1000-word critical essays discussing the Ethical, Legal, and Regulatory issues covered in Parts I through III. The essays will be evaluated on the basis of effective writing and content. Prior to each assignment, class time will be devoted to address effective writing in the academic discipline. One week after the writing assignments are due, the students will be provided with extensive feedback and will be given an opportunity to submit a revised version of each assignment. Grades will be based on the quality of the original submissions and the revisions

**Grading**

The grade for this course will be based on class participation, two midterm exams plus a non-comprehensive final exam, and three writing assignments.

| | | Subtotals |
|---|---|---|
| Writing assignments | 10 % | 30 % |
| Midterm exams | 20 % | 40 % |
| Final exam | 25 % | 25 % |
| Class participation | 5 % | 5 % |
| Total | | 100 % |