COURSE SYLLABUS

Ethics in Biopharmaceutical Patent and Regulatory Law
Spring 2024, Biotechnology GU4161

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Course Objective

This course – the first of its kind at Columbia – introduces students to a vital subfield of ethics focusing on patent and regulatory law in the biotech and pharmaceutical sectors. The course combines lectures, structured debate, and research to best present this fascinating and nuanced subject. Properly exploring this branch of bioethics requires a sufficient understanding of biotech and pharmaceutical patent and regulatory law. Students can gain this understanding by first completing Biotechnology Law (BIOT GU4160), formerly the prerequisite for this course. They can also gain it by reading the appropriate chapters of *Biotechnology Law: A Primer for Scientists* prior to each class.

Course Overview

In recent years, ethics disputes relating to biotech and pharmaceutical patent and regulatory law have become ubiquitous. The news has been filled with stories of public outrage over everything from denial of compassionate drug use to unaffordable biologic drugs, and from authorized generics to so called "pay-for-delay" settlement agreements between generic and brand name drug companies. These issues, and many more, show just how often biotech and pharmaceutical patent and regulatory laws conflict with society's sense of right and wrong.

Legislatures, courts, and industry leaders alike continue to address these controversies through law, policy, and practice as best they can. Yet, such efforts often fall short.

Understanding these important ethics issues naturally requires familiarity with the underlying science and law. However, identifying, understanding, writing about, debating, and resolving ethics issues – particularly those at the crossroads of such complex fields – also requires practice. This course offers precisely that.

Toward that end, the course combines three approaches: (i) traditional lectures with questions and discussion as needed; (ii) student research papers (i.e., "position" papers);

and (iii) structured student-on-student debates. The research papers and debates warrant some brief remarks here.

Research Assignments

Each student will write three research papers. The first two papers will address ethics issues of the student's own choosing, and the third will address an assigned issue. The Research Writing Assignments Memorandum provides all details regarding these assignments.

Briefly, though, in each four-page research paper, the student will engage in written role-playing by separately advocating *both sides* of the ethics issue. Each side will be advocated *as a defined figure* (e.g., a CEO, NGO leader, or government official) likely to take that side of the issue.

These assignments improve writing ability generally. Importantly, they also strengthen the student's ability to identify and deal with weaknesses in a given position on an issue.

Debates

The debates will also stress role-playing and will be akin to interactive panel discussions and news interviews conducted between opposing parties. For example, in a debate, one student might assume the role of a biotech company's CEO, while the other would play the director of a patient advocacy group opposed to the company's allegedly unethical patent and pricing strategies. These exercises differ in format, tone, and purpose from traditional debates where, typically, the emphasis is on scoring as many points as possible within a given time limit. Here, our goal is to be as persuasive as possible given the scenario at hand – a task often best accomplished by slowly and artfully making one or two key points.

Most debates during the first part of the semester will be one-on-one. After that, most debates will be group-on-group. Importantly, students will *switch positions* mid-debate so that they can reap the benefits of arguing both sides of each issue.

The use of debates and position-based research papers will arm qualified students with vital skills throughout their careers in science, industry, venture capital, and government. These include the ability to spot and understand patent and regulatory ethics issues, lead others in navigating them and, when necessary, persuade others of the merits of one position over another.

Each of the three research papers is worth one third of the course grade. Participation in the debates is required but will not be graded.

Class Schedule

The class schedule is provided below. Within reason, the material to be covered is subject to change, particularly to accommodate changes in the law and the addition of relevant topics based on student demand. Likewise, the timing of each class relative to its corresponding debate is also subject to change.

Class 1 – January 16, 2024

Course overview.

Lecture 1 – The practice of "compassionate use" by a drug company, whereby the company provides its investigational new drug to a critically ill patient outside the context of a clinical trial, *before* the FDA approves the company's NDA or BLA for the drug. This practice's potential risks and benefits for drug companies, compassionate use recipients, and target patient populations.

Class 2 – January 23, 2024

Debate 1 – Compassionate use.

Lecture 2 – Litigious corporate behavior in the agricultural biotech industry, and the ethical tension between legitimately defending one's own patent rights and pursuing individual farmers and merchants suspected of *unintentional* infringement. The matter of Monsanto's right to assert its Roundup Ready® seed patents against unintentionally infringing organic farmers.

Class 3 – January 30, 2024

Debate 2 – Agricultural patent enforcement.

Lecture 3 – Ethically flawed informed consent procedures in foreign clinical trials. The question of which informed consent standard should apply to a U.S. drug company conducting a trial in a developing country. The case of *Abdullahi v. Pfizer* and Pfizer's catastrophic Nigerian Trovan® trial in 1996.

Class 4 – February 6, 2024

Debate 3 – Informed consent procedures in foreign clinical trials.

Lecture 4 – The recently implemented federal statute governing the labeling of GMO foods in the United States. The ethical facets of the new regulations, which permit disclosing GMO status solely via computer link or phone rather than through a food label per se.

Class 5 – February 13, 2024

Debate 4 – GMO labeling

Lecture 5 – The limits of the Declaratory Judgment Act regarding a non-profit organization's ability to challenge an innovator company's drug patents. The case of *AIDS Healthcare Foundation, Inc. v. Gilead Sciences, Inc.*, and Gilead's anti-HIV tenofovir products.

Class 6 – February 20, 2024

Debate 5 – Pharmaceutical declaratory judgment actions.

Lecture 6 – The ethics of using trade secret protection with respect to the genetic information of another. Myriad Genetics' reliance on trade secret protection in maintaining a proprietary database of correlations between specific BRCA1/2 gene mutations and cancer prognoses, and this business model's implications for healthcare transparency and the patient's right to understand her own prognosis and its underlying genetic basis.

Class 7 – February 27, 2024

Debate 6 – Keeping genetic information as a trade secret.

Lecture 7 – The controversial practice of "product hopping" in the pharmaceutical industry used to prolong market dominance for a drug beyond the expiration of its earliest filed patents. The case of *New York v. Actavis*, and the anti-trust implications of Actavis' plan to thwart generic competition by prematurely withdrawing its Alzheimer's drug Namenda IR from the market and replacing it with its newer product Namenda XR.

Class 8 – March 5, 2024

Debate 7 – Product hopping.

Lecture 8 – The practice whereby an innovator company concurrently sells its drug as a brand-name product *and* as a generic product – known as an "authorized generic." The ethics of selling an authorized generic product during the 180-day ANDA exclusivity period granted to the first generic company to challenge the innovator company's drug patents.

Class 9 – March 19, 2024

Debate 8 – Authorized generics.

Lecture 9 – The role of Risk Evaluation and Mitigation Strategies (REMS) in the FDA's drug approval scheme. The case of Celgene's REMS for its anti-cancer drugs Thalomid® and Revlimid®, and assertions by generic competitors that they violate antitrust law. The litigation between Celgene and Mylan regarding Celgene's conduct in this regard.

Class 10 – March 26, 2024

Debate 9 – REMS.

Lecture 10 – The practice of publicly challenging a pharmaceutical company's patents via *inter partes* review while, at the same time, financially benefitting from "shorting" that company's stock. The case of hedge fund manager Kyle Bass and his Coalition for Affordable Drugs.

Class 11 – April 2, 2024

Debate 10 – Pharmaceutical stock shorting via IPR patent challenges.

Lecture 11 – Emerging ethics issue 1 in biopharmaceutical patent and regulatory law [tbd].

Class 12 – April 9, 2024

Debate 11 – Emerging ethics issue 1 in biopharmaceutical patent and regulatory law [tbd].

Lecture 12 – Emerging ethics issue 2 in biopharmaceutical patent and regulatory law [tbd].

Class 13 – April 16, 2024

Debate 12 – Emerging ethics issue 2 in biopharmaceutical patent and regulatory law [tbd].

Class 14 – April 23, 2024

Students briefly present their research papers, as time permits.

Preliminary Reading List

A. Caplan and K. Moch, "Rescue Me: The Challenge Of Compassionate Use In The Social Media Era", Health Affairs Blog (2014)
http://healthaffairs.org/blog/2014/08/27/rescue-me-the-challenge-of-compassionate-use-in-the-social-media-era/

C. Klugman, "Cost of Compassionate Use is Simply Too High", Bioethics Research Library of Georgetown University (2015)
https://bioethics.georgetown.edu/2015/05/cost-of-compassionate-use-is-simply-too-high/

OSGATA v. Monsanto, Petition for Writ of Certiorari to the U.S. Supreme Court (2013)
http://www.pubpat.org/assets/files/seed/OrganicSeedSCTPetition.pdf

C. Silver, "Monsanto versus the people", Al Jazeera (2013)
http://www.aljazeera.com/indepth/opinion/2013/01/201311071754973439.html

G. Annas, "Globalized Clinical Trials and Informed Consent", N.E.J.M. 360:20 (2009)
http://www.ncbi.nlm.nih.gov/pubmed/19439740

M. Afolabi, et al., "Informed consent comprehension in African research settings", Tropical Medicine and International Health, Vol. 19, No. 6, pp. 625-642 (2014)
http://onlinelibrary.wiley.com/doi/10.1111/tmi.12288/epdf

Abdullahi v. Pfizer, 562 F.3d 163 (2d Cir. 2009)
https://casetext.com/case/abdullahi-v-pfizer-inc

A. Harmon, "G.M.O. Foods Will Soon Require Labels. What Will the Labels Say?", New York Times (2018)
https://www.nytimes.com/2018/05/12/us/gmo-food-labels-usda.html

"National Bioengineered Food Disclosure Standard", Federal Register (December 21, 2018)
https://www.federalregister.gov/documents/2018/12/21/2018-27283/national-bioengineered-food-disclosure-standard

C. Siegner, "USDA issues final GMO-labeling guidelines for food", FoodDive (December 21, 2018)
https://www.fooddive.com/news/usda-issues-final-gmo-labeling-guidelines-for-food/544944/

AIDS Healthcare Foundation v. Gilead, U.S. Federal Circuit Decision (2018)
https://foiadocuments.uspto.gov/federal/16-2475_1.pdf

AIDS Healthcare Foundation v. Gilead, Petition for Cert. to the U.S. Supreme Court (Denied)
https://www.aidshealth.org/wp-content/uploads/2018/08/36429-cert-petition.pdf

R. Cook-Deegan, et al., "The Next Controversy in Genetic Testing: Clinical Data as Trade Secrets?", European J. of Human Genetics (2012)
http://www.nature.com/ejhg/journal/v21/n6/full/ejhg2012217a.html

New York v. Actavis, No. 14-4624 (2nd Cir., May 22, 2015)
http://www.ag.ny.gov/sites/default/files/pdfs/bureaus/antitrust/NY_v.Actavis-CA2_public_opinion.pdf

M.S. Royall, et al., "Antitrust Scrutiny of Pharmaceutical 'Product Hopping'", Antitrust (2013)
http://www.gibsondunn.com/publications/Documents/RoyallAntitrustScrutinyABA.pdf

Z. Brennan, "Authorized Generics: Why Mylan Would Compete With Itself in the EpiPen Market", Regulatory Focus (2016)
https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2016/8/authorized-generics-why-mylan-would-compete-with-itself-in-the-epipen-market

"Authorized Generics", Global Policy & International Public Affairs, Pfizer (2018)
https://www.pfizer.com/files/about/Authorized_Generics_2018.pdf

N.S. Banait, "Authorized Generics: Antitrust Issues and the Hatch-Waxman Act", Fenwick & West LLP (2005)
https://www.fenwick.com/FenwickDocuments/Authorized_Generics.pdf

"FDA Basics Webinar: A Brief Overview of Risk Evaluation and Mitigation Strategies (REMS)", FDA Website
https://www.fda.gov/aboutfda/transparency/basics/ucm325201.htm

"Risk Evaluation and Mitigation Strategies: Modifications and Revisions Guidance for Industry", CDER and CBER (2015)
https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm441226.pdf

T. Sullivan, "Antitrust Lawsuit Against Celgene Over Thalomid and Revlimid Focuses on REMS Requirements", Policy & Medicine (2018)
https://www.policymed.com/2014/08/antitrust-lawsuit-against-celgene-over-thalomid-and-revlimid-focuses-on-rems-requirements.html

J. Walker and R. Copeland, "New Hedge Fund Strategy: Dispute the Patent, Short the Stock", The Wall Street Journal (2014)
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