



**INTELLECTUAL PROPERTY ADVOCACY, POLICY AND ACCESS: A STUDY OF THE *MYRIAD* GENE
PATENTING LITIGATION
(LAW _____)**

Professor Contreras

Spring 2025, 1 credit
Feb. 8 and Feb. 22, 2025
9:00 am to 4:00 pm, Room _____

[*version May 28, 2024*]

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Office Hours: by appointment (by Zoom or in-office)

TEXT

JORGE L. CONTRERAS, *THE GENOME DEFENSE: INSIDE THE EPIC LEGAL BATTLE TO DETERMINE WHO OWNS YOUR DNA* (ALGONQUIN, 2021)¹

WEBSITE: [HTTPS://GENOMEDEFENSE.ORG](https://genomedefense.org)

COURSE DESCRIPTION

In 2013, the U.S. Supreme Court decided *Association for Molecular Pathology v. Myriad Genetics*, the landmark case that banned the patenting of human genes. Beyond this narrow (though important) interpretation of Section 101 of the Patent Act, *Myriad* was brought and prosecuted by the ACLU largely as a civil rights case. It highlights the deep divide in the United States between those who view patents as fuel for the “fire of genius” versus those who view them as impediments to the equitable distribution of lifesaving drugs and diagnostics. *Myriad* raised issues concerning women’s health, access to medicine, healthcare reimbursement and innovation policy. As a matter of litigation strategy, *Myriad* demonstrated how public interest advocacy should be pursued in highly technical cases, how coalitions of interest are formed, and

¹ In accordance with *University Policy 6-316 (Rev. 11): Code of Faculty Rights and Responsibilities, Section 4.B.10.b*, an instructor may not profit from the sale of materials assigned in that instructor’s class. Accordingly, any profit earned by the instructor from sales of the book for this class will be contributed to “a tax exempt organization” (in this case, the COL student scholarship fund).

how public communication and media influence the outcome of major cases. Finally, *Myriad* sheds light on the complex and little-known world of federal agency politics, and how the federal government intervenes in private litigation to achieve public goals. This class will explore these many facets of the *Myriad* litigation and decisions, allowing students to discuss and debate issues that are more timely than ever today.

PREPARATION

Students must read the entire book assigned for the class (including the Appendix and Notes), and to prepare responses to discussion questions as described below, prior to the beginning of the first class. Any student who is unable to complete this work prior to the first class is encouraged to withdraw from the class prior to its commencement.

LEARNING OUTCOMES

Upon successful completion of this course, it is expected that students will gain the following skills and substantive knowledge:

1. Understand the Supreme Court's and lower courts' reasoning and holdings in *Myriad* with respect to the patenting of naturally occurring substances;
2. Understand the implications of the *Myriad* decision for various stakeholder constituencies, including the biotechnology industry, the patent bar, researchers and individual patients;
3. Understand the historical development of the "product of nature" doctrine, as well as the cultural, social and scientific forces that shaped it over the years;
4. Understand how biomedical research is funded in the United States, and the role that universities, venture capital and private companies play in R&D;
5. Understand how the insurance industry, including government-funded programs such as Medicare and Medicaid, shapes health policy and the availability of healthcare products;
6. Understand the ethical issues surrounding genetic testing and diagnostics, and how our understanding of these issues has evolved over time;
7. Understand how a public interest legal campaign is mounted, including how coalitions are built
8. Understand how the media are used in impact litigation, and how independent media, such as bloggers, can influence public opinion alongside traditional media outlets;
9. Understand the role of the federal government in private litigation, including the role of the Solicitor General and how positions are developed among competing federal agencies;
10. Gain a better appreciation for the manner in which the common law evolves in response to individual cases and events.

TEACHING AND LEARNING METHODS

This course will be taught primarily as an interactive class discussion, centering on previously distributed discussion questions. A writing assignment will be required.

KEY COURSE POLICIES

ATTENDANCE

This class consists of only two live class sessions. In-person attendance during the entire duration of both class sessions is mandatory in order to receive credit for the class. There are no excused absences. If illness, accident or some other circumstance prevents a student from attending the entirety of both class sessions, that student should withdraw from the class. The class will not be recorded or broadcast via Zoom.

GRADING

Grades for this class will be assigned as follows:

Writing Assignment	56%
Discussion Leader	24%
Class participation	20%
TOTAL	100%

The COL mandatory curve does not apply with respect to this class. Grades will be assigned based on each student’s individual performance and the overall distribution of scores within the class, each as determined by the instructor in his sole discretion.

DISCUSSION LEADER

This class will be centered around fourteen different discussion topics drawn from the text. The list of topics, as well as a number of discussion questions for each topic, will posted on the Class Schedule document in Canvas on or before the beginning of the semester.

Each student must lead the discussion of one of these topics (A-M). Students must sign-up for the topic of their choice via the Canvas Discussion feature. Some topics can accommodate two discussion leaders, others are only suitable for one. This breakdown is listed on the Discussion board. Sign-up is first come, first served. Students may trade topics with other students, so long as the finalized list of discussants is clear by the beginning of the first class.

Discussion leaders are responsible for leading an in-class discussion of their selected topic, including all of the Discussion Questions posted for that topic. At a minimum, discussion leaders should have read all text from the book relating to their topic (including the Appendix and Notes), as well as materials, as applicable from the online Primary Documents and References (posted on the book website). Additional research and reading are encouraged.

Discussion leaders will be graded based on the depth of their knowledge of the topic and the quality of their discussion.

CLASS DISCUSSION

In addition to the topic on which students act as Discussion Leaders, all students are expected to engage meaningfully in the discussion of the other topics covered in the class.

WRITING ASSIGNMENT

Each student is required to complete a written assignment as part of this class. The assignment is due (via Canvas) no later than 5 pm MT on **March 5, 2025**.

The assignment consists of answering, in writing, seven of the Discussion Questions for the class. These Discussion Questions must relate to topics as to which the submitter was NOT a discussion leader. Each Discussion Question answered must come from a different topic (i.e., you may choose to answer one question from topic A, one from topic C, one from topic F, and so on).

Each answer should be at least 300 words in length (and can be longer). Each answer should be identified by the topic name, letter (A-N) and question number. The question text should be reproduced above each answer. The text of questions does not count toward the 300-word minimum for each answer. Do not use IRAC or other contrived formats. Just answer the questions.

Answers will be graded based on accuracy, completeness, relevance, originality, coherence, logic and following instructions. Points will be deducted for grammatical and spelling errors, so proofread carefully. Answers below the word minimum will not be scored. Each question will be graded on an 8-point scale.

OTHER CLASS POLICIES AND PROCEDURES

ANNOUNCEMENTS

The instructor will make class announcements via email (addressed to whatever email account is linked to students' university Canvas account). Students are responsible for checking their university email regularly and reading all announcements.

ARTIFICIAL INTELLIGENCE

You are welcome to use artificial intelligence, machine learning and other advanced technologies (“AI”) to aid you in reading and preparing for this class. Please let the instructor know if you find AI technologies that are particularly useful in the context of this class.

However, all written work must be prepared by the student without assistance from any AI or other person. Using an AI to draft, outline or prepare any written work submitted in this class constitutes a violation of the Student Code and will result in immediate removal of the student from this class without credit.

CLASS RECORDINGS - NONE

Given the interactive nature of this class, the anticipated use of the white board, the frequency of in-class exercise, and the limited capabilities of the COL’s recording technology, this class will not be recorded and will not be available via Zoom. Students are welcome to record class sessions using their own recording devices purely for their own study purposes and to share with other enrolled classmates. Sharing, distributing or posting class recordings outside of these parameters is strictly forbidden and constitutes a violation of University policy that will result in the student’s immediate removal from the class without credit.

IN-CLASS CONDUCT

Use of laptop computers and tablet devices in class is permitted for note-taking and other authorized purposes only. The use of computers, tablets, texting devices and mobile telephones during class for playing games, checking messages, communicating with classmates, web surfing and other purposes unrelated to class is distracting to the instructor and your classmates and is thus prohibited. If you engage in such activity, the instructor reserves the right to prohibit further device usage by you for the duration of the semester. The participation component of your final grade will also be adjusted accordingly.

SYLLABUS

This syllabus serves as a general guide as to how this class will be conducted. You are expected to understand all class requirements described in this document.

UNIVERSITY POLICIES AND PROCEDURES

- 1. ACADEMIC MISCONDUCT.** COL Policy 6-400 (Student Code) applies to this class. Students should take note of Sections V.B and I.B.2 of the Student Code relating to “academic misconduct”. Academic misconduct includes plagiarism, which is defined as “the intentional unacknowledged use or incorporation of any other person's work in, or as a basis for, one's own work offered for academic consideration or credit or for public presentation. Plagiarism includes, but is not limited to, representing as one's own, without attribution, any other individual's words, phrasing, ideas, sequence of ideas, information or any other mode or content of expression.” All Final Papers submitted for this class will be scanned by an automated plagiarism detector. Any positive result will be referred to the appropriate disciplinary authorities. Pursuant to Section V.B of the Student Code, “A student who engages in academic misconduct as defined in Part I.B. may be subject to academic sanctions including but not limited to a grade reduction, failing grade, probation, suspension or dismissal from the program or the University, or revocation of the student's degree or certificate.”
- 2. Campus Safety.** The University of Utah values the safety of all campus community members. To report suspicious activity, call campus police at 801-585-COPS (801-585-2677). You will receive important emergency alerts and safety messages regarding campus safety via text message. For more information regarding safety and to view available training resources, including helpful videos, visit safeu.utah.edu.
- 3. The Americans with Disabilities Act.** The University of Utah seeks to provide equal access to its programs, services, and activities for people with disabilities. If you will need accommodations in this class, reasonable prior notice needs to be given to the Center for Disability Services, 162 Olpin Union Building, (801) 581-5020. CDS will work with you and the instructor to make arrangements for accommodations. All written information in this course can be made available in an alternative format with prior notification to the Center for Disability Services.
- 4. Addressing Sexual Misconduct.** Title IX makes it clear that violence and harassment based on sex and gender (which includes sexual orientation and gender identity/expression) is a civil rights offense subject to the same kinds of accountability and the same kinds of support applied to offenses against other protected categories such as race, national origin, color, religion, age, status as a person with a disability, veteran's status or genetic information. If you or someone you know has been harassed or assaulted, you are encouraged to report it to the Title IX Coordinator in the Office of Equal Opportunity and Affirmative Action, 135 Park Building, 801-581-8365, or the Office of the Dean of Students, 270 Union Building, 801-581-7066. For support and confidential consultation, contact the Center for Student Wellness, 426 SSB, 801-581-7776. For off-campus resources, contact the Utah Domestic Violence Coalition at 1-800-897-5465. To report to the police, contact the Department of Public Safety, 801-585-2677(COPS).
- 5. Drop/Withdrawal.** Please check the University of Utah's academic calendar for information pertaining to drop and withdrawal dates. Withdrawing from a course and other matters of registration are the student's responsibility. <http://registrar.utah.edu/academic-calendars/>
- 6. Wellness Statement.** Personal concerns such as stress, anxiety, relationship difficulties, depression, cross-cultural differences, etc., can interfere with a student's ability to succeed and thrive at the University of Utah. For helpful resources contact the Center for Student Wellness at www.wellness.utah.edu or 801-581-7776.
- 7. Veterans Center.** If you are a student veteran, the University of Utah has a Veterans Support center located in Room 161 in the Olpin Union Building. Please visit their website for more information about what support they offer, a list of ongoing events and links to outside resources: <http://veteranscenter.utah.edu>.

- 8. LGBTQ+ Issues.** If you are a member of the LGBTQ+ community, please be assured this class is a safe zone. Your views will be treated with respect and attention. Additionally, the University of Utah has an LGBT resource center on campus. It is located in Room 409 of the Olpin Union Building. You can visit its website to find more information about the support it can offer, a list of events through the center and links to additional resources: <http://lgbt.utah.edu>.
- 9. Student Names and Personal Pronouns:** Class rosters are provided to the instructor with each student's legal name as well as "Preferred first name" (if previously entered by you in the Student Profile section of your CIS account, which can be managed at any time). The instructor will use reasonable efforts to refer to you by the name and pronoun that you specify in advance in writing. Please advise the instructor of any name or pronoun changes that occur during the course of the semester. If you need any assistance or support in this regard, please contact the LGBT Resource Center. https://lgbt.utah.edu/campus/faculty_resources.php
- 10. Learners of English as an Additional/Second Language.** If you are an English language learner, please be aware of several resources on campus that will support you with your language and writing development. These resources include: the writing Center (<http://writingcenter.utah.edu>); the Writing Program (<http://writing-program.utah.edu>); the English Language Institute (<http://continue.utah.edu/eli>).
- 11. Diversity/Inclusivity Statement.** It is the instructor's intent that students from all diverse backgrounds and perspectives be well served by this course, that students' learning needs be addressed both in and out of class, and that the diversity that students bring to this class be viewed as a resource, strength and benefit. It is the instructor's intent to present materials and activities that are respectful of diversity: gender, sexuality, disability, age, socioeconomic status, ethnicity, race, and culture. Your suggestions are encouraged and appreciated. Please let the instructor know ways to improve the effectiveness of the course for you personally or for other students or student groups. In addition, if any class meetings conflict with your religious events, please let the instructor know as soon as possible so that alternative arrangements can be considered.
- 12. Student Code**
The Student Code for the University of Utah applies to this class. It can be found at: <http://regulations.utah.edu/academics/6-400.php>.