UNIVERSITY OF FLORIDA
FREDRIC G. LEVIN COLLEGE OF LAW

Patents & Biotechnology
Law 6930
Course 27407

August 11-14, 2025
Mon: 11:00-11:50 & 1:00-2:50
Tue & Wed: 10:00-11:50 & 2:00-3:50
Thurs: 9:00-9:50 & 1:00-2:50
Holland Hall 345

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Office Hours:
Wednesday 9:00-10:00
Thurs 11:00-12:00
College of Law Courtyard

COURSE DESCRIPTION AND OBJECTIVES

This course provides students with an understanding of biotechnology as an industry and discusses the differences between US and international biotech patent law. It also analyzes issues related to two areas of patenting and biotech: monoclonal antibodies and CRISPR. Although helpful, students need not to have taken patent law to enroll in this course. The instructor will provide an overview of the essential components of patent law that pertain to this course on the first day.

LEARNING OUTCOMES

After completing this course, students will be able to:

- identify and analyze legal issues relating to patenting and biotechnology;
- identify the differences between US and OUS patenting in biotechnology;
- identify and analyze written description and enablement issues relating to monoclonal antibodies; and

- identify and analyze legal issues relating to CRISPR

REQUIRED TEXTS

No textbook is required. Required readings are online or will be provided in pdf format on Canvas.

CLASS PARTICIPATION

Thirty percent (30%) of your final grade will be based on your class participation. Each day I expect that you will have read the assigned materials and that you will be prepared to discuss those materials. There will be several patent activities that will be homework and then reviewed together. The expectation is that you will be prepared to meaningfully participate in each of those activities.

COMMON COURTESY

Please do not arrive late to class, leave early, or leave to take a break during class absent extenuating circumstances. Please turn off your cell phone during class. I reserve the right to deduct points from your final grade if you engage in behavior that disrupts the learning environment for your classmates.

CLASS ATTENDANCE POLICY

Attendance in class is required by both the ABA and the Law School. I will pass around an attendance sheet at the beginning of each class period. If you have a medical reason for missing class, you should contact me before or soon after class for your absence to be excused. Students who miss class for religious holidays must contact me beforehand by email to be excused from class. I will consider it a violation of the honor code if you have someone else sign you in and you are not present, and I reserve the right to lower your final grade.

EVALUATION

Seventy percent (70%) of your grade will be based on a final examination administered on August 29, 2025. During the exam you may use any notes or outlines that you have prepared or helped prepare (partial open book), but you will not be permitted to use the Internet or any other materials.

INFORMATION ON UF LAW GRADING POLICIES

The law school grading policy is available at: https://www.law.ufl.edu/life-at-uf-law/office-of-student-affairs/current-students/uf-law-student-handbook-and-academic-policies.

ACADEMIC HONESTY

Academic honesty and integrity are fundamental values of the University community. Students should be sure that they understand the UF Student Honor Code at http://www.dso.ufl.edu/students.php.

POLICY RELATED TO MAKE-UP EXAMS

The law school policy on delay in taking exams can be found at: http://www.law.ufl.edu/student-affairs/current-students/forms-applications/exam-delays-accommodations-form

STATEMENT RELATED TO ACCOMODATIONS FOR STUDENTS WITH DISABILITIES

Students requesting accommodation for disabilities must first register with the Disability Resource Center (http://www.dso.ufl.edu/drc/). Once registered, students will receive an accommodation letter which must be presented to the Assistant Dean for Student Affairs (Dean Mitchell) when requesting accommodation. Students with disabilities should follow this procedure as early as possible in the semester.

COURSE WORKLOAD AND CLASS PREPARATION

Students should expect to spend at least two hours outside of class reading and preparing for every hour of class.

RECORDINGS OF CLASS

Students are allowed to record video or audio of class lectures. However, the purposes for which these recordings may be used are strictly controlled. The only allowable purposes are (1) for personal educational use, (2) in connection with a complaint to the university, or (3) as evidence in, or in preparation for, a criminal or civil proceeding. All other purposes are prohibited. Specifically, students may not publish recorded lectures without the written consent of the instructor. A "class lecture" is an educational presentation intended to inform or teach enrolled students about a particular subject, including any instructor-led discussions that form part of the presentation, and delivered by any instructor hired or appointed by the University, or by a guest instructor, as part of a University of Florida course. A class lecture does not include lab sessions, student presentations, clinical presentations such as patient history, academic exercises involving solely student participation, assessments (quizzes, tests, exams), field trips, private conversations between students in the class or between a student and the faculty or guest lecturer during a class session. Publication without permission of the instructor is prohibited. To "publish" means to share, transmit, circulate, distribute, or provide access to a recording, regardless of format or medium, to another person (or persons), including but not limited to another student within the same class section. Additionally, a recording, or transcript of a recording, is considered published if it is posted on or uploaded to, in whole or in part, any media platform, including but not limited to social media, book, magazine, newspaper, leaflet, or third-party note/tutoring services. A student who publishes a recording without written consent may be subject to a civil cause of action instituted by a person injured by the publication and/or discipline under UF Regulation 4.040 Student Honor and Student Conduct Code.

TOPICAL OUTLINE OF SUBJECTS TO BE COVERED

The outline below generally represents what I will attempt to cover during class periods. There will be three blocks of subjects specific to biotechnology—1) patent subject matter eligibility; 2) monoclonal antibodies; and 3) CRISPR. We may move faster or slower depending on how the classes progress and resulting discussions, especially with our guest speakers. At some point after the end of each class, I will inform you of the reading I will attempt to cover during the next class. The readings below are the tentative readings and can be subject to change due to time constraints and/or new opinions. Nevertheless, you can anticipate what the next class period's reading assignment will be from the outline below if you wish to read ahead.

1. **Patents**
   Review Lecture

2. **Biotechnology as an Industry**
   a. Background reading on what is biotech
      Varsha Gupta, Manjistha Sengupta, Jaya Prakash, et al., *An Introduction to Biotechnology*. In: BASIC AND APPLIED ASPECTS OF BIOTECHNOLOGY, at 1-21 (Chapter 1) (2017). https://doi.org/10.1007/978-981-10-0875-7_1
   b. Economic Incentive to Patent
      (the following two articles are to be read for interest and short class discussion but will not be on the exam)
      i. Ted Sichelman & Stuart J. Graham, *Patenting by Entrepreneurs: An Empirical Study*, 17 MICH. TELECOMM. & TECH. L. REV. 111 (2010) https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1040&context=mttlr
      ii. Ted Buckley, *The Myth of the Anticommons,* May 31, 2007 https://archive.bio.org/sites/default/files/TheMythoftheAnticommons.pdf

3. **Biotech Patent Subject Matter Eligibility**
   a. U.S. Subject Matter Eligibility Cases
      i. *Mayo Collaborative Servs. v. Prometheus Lab., Inc*., 566 U.S. 66 (2012)
      ii. *Ass'n. for Molecular Pathol. v. Myriad Genetics Inc.*, 569 U.S. 576 (2013)
      iii. *Ariosa Diagnostics, Inc.* v. *Sequenom, Inc*., 788 F.3d 1371 (Fed. Cir. 2015)
      iv. *Rapid Litig. Mgmt. Ltd. v. Cellzdirect, Inc.,* 827 F.3d 1042 (Fed. Cir. 2016)
      v. *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018)*
      vi. *Illumina, Inc. v. Ariosa Diagnostics, Inc.,* No. 2019-1419 (Fed. Cir. 2020)
   b. OUS *Myriad* DNA Subject Matter Eligibility Cases
      i. EPO Case No. T 1213/05 (27 Sept. 2007) (Paragraphs 43 to 57 of the Reasons for the Decision at pages 46-54)
      ii. EPO Case No. T 0080/05 (19 Nov. 2008) (Paragraphs 56 to 65 of the Decision at pages 36-39)
      iii. *D'Arcy v. Myriad Genetics, Inc*. (2015) HCA 35

c. OUS *Ariosa* Diagnostic Subject Matter Eligibility Cases
   i. *Ariosa Diagnostics, Inc.* v. *Sequenom, Inc*., (2021) FCAFC 101 (Paragraphs 76 to 167)
   ii. *Illumina, Inc.* v *Premaitha Health Plc* (2017) EWHC 2930 (Pat) Carr. J. (Paragraphs 184 to 189)

4. § 112 Issues with Monoclonal Antibodies

a. Background Reading on the Therapeutic Antibody Technology
   i. Lu, RM., Hwang, YC., Liu, IJ. *et al.* Development of therapeutic antibodies for the treatment of diseases. *J Biomed Sci* **27,** 1 (2020). https://jbiomedsci.biomedcentral.com/articles/10.1186/s12929-019-0592-z
   ii. Wang, Y. What are Monoclonal Antibodies? (2021). https://www.rapidnovor.com/what-are-monoclonal-antibodies/

b. Cases
   i. *Centocor Ortho Biotech, Inc. v. Abbott Labs*., 636 F.3d 1341 (Fed. Cir. 2011)
   ii. *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014)
   iii. *Amgen Inc. v. Sanofi*, 872 F. 3d 1367 (Fed. Cir. 2017)
   iv. *Amgen Inc. v. Sanofi*, 987 F.3d 1080 (Fed. Cir. 2021)
   v. *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023)

5. CRISPR

a. Background Reading on the CRISPR Technology
   Adli, M., The CRISPR tool kit for genome editing and beyond, *Nature Communications* 9, 1911 (2018). https://doi.org/10.1038/s41467-018-04252-2

b. Cases
   i. Regents of the Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286 (Fed. Cir. 2018)
   ii. Regents of the Univ. of Cal. v. Broad Inst., Inc., Patent Interference No. 106,115 (PTAB 2022)
   iii. Regents of the Univ. of Cal. v. Broad Inst., Inc., __ F.4th __, 2025 U.S. App. LEXIS 11373, 2025 WL 1363125 (Fed. Cir. 2025)

GUEST SPEAKERS

1. **Richard Linn, Circuit Judge, United States Court of Appeals for the Federal Circuit**, has agreed to join the class to discuss the state of patent subject matter eligibility. https://www.linninn.org/About/

2. ***Prashant Girinath, J.D., Ph.D.*, Shareholder, Greenberg Traurig LLP**, will join the class to discuss the state of CRISPR patents. Dr. Girinath designs and implements IP strategy for numerous biotech clients. One client is Mammoth Biosciences, which is an early stage company co-founded by Nobel laureate Jennifer Doudna and is developing products based on the CRISPR platform. https://www.gtlaw.com/en/professionals/g/girinath-prashant