**UNIVERSITY OF FLORIDA**

**FREDERIC G. LEVIN COLLEGE OF LAW**

**Patents & Biotechnology**

**Law 6930**

**Course 27407**

***August 16-19, 2021***

***Mon & Thurs: 11:00-11:50 & 1:00-2:50***

***Tue & Wed: 10:00-11:50 & 2:00-3:50***

Holland Hall 283

**Brian R. Dorn, J.D., Ph.D.**

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Office Hours:

Wednesday 9:00-10:00

Thurs 10:00-11:00

College of Law Courtyard

**COURSE 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 September 10, 2021. 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.

**STATEMENT RELATED TO IN-CLASS RECORDINGS**

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 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 Code and Student Conduct Code.

**COURSE EVALUATION**

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Click here for guidance on how to give feedback in a professional and respectful manner. Students will be notified when the evaluation period opens and may complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via <https://ufl.bluera.com/ufl/>. Summaries of course evaluation results are available to students [here](https://gatorevals.aa.ufl.edu/public-results/).

**TOPICAL OUTLINE OF SUBJECTS TO BE COVERED**

The outline below generally represents what I will attempt to cover during class periods. There will be four blocks of subjects specific to biotechnology—1) patent subject matter eligibility; 2) differences in US and OUS patenting; 3) monoclonal antibodies; and 4) 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

1. **Biotechnology as an Industry**
   1. 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>

* 1. Economic Incentive to Patent
     1. Ted Sichelman & Stuart J. Graham, *Patenting by Entrepreneurs: An Empirical Study*, 17 Mich. Telecomm. & Tech. L. Rev. 111 (2010)
     2. Ted Buckley, *The Myth of the Anticommons,* May 31, 2007

[https://www.bio.org/sites/default/files/legacy/bioorg/docs/TheMythofthe](https://www.bio.org/sites/default/files/legacy/bioorg/docs/TheMythoftheAnticommons.pdf)

[Anticommons.pdf](https://www.bio.org/sites/default/files/legacy/bioorg/docs/TheMythoftheAnticommons.pdf)

* 1. Subject Matter Eligibility Cases
     1. *Mayo Collaborative Servs. v. Prometheus Lab., Inc*., 566 U.S. 66 (2012)
     2. *Ass’n. for Molecular Pathol. v. Myriad Genetics Inc.*, 569 U.S. 576 (2013)
     3. *Ariosa Diagnostics, Inc.* v. *Sequenom, Inc*., 788 F.3d 1371 (Fed. Cir. 2015)
     4. *Illumina, Inc. v. Ariosa Diagnostics, Inc.,* No. 2019-1419 (Fed. Cir. 2020)

1. **Differences in International Biotech Patent Law**
   1. Stem Cells
      1. Article 53(a) EPC
      2. EPO Case No. G 0002/06 (25 November 2008)
      3. *International Stem Cell Corp*.*,* (2016) APO 52
   2. *Myriad* DNA Subject Matter Eligibility Cases
      1. EPO Case No. T 1213/05 (27 Sept. 2007)
      2. EPO Case No. T 0080/05 (19 Nov. 2008)
      3. *D’Arcy v. Myriad Genetics, Inc*., (2015) HCA 35
   3. *Ariosa* Diagnostic Subject Matter Eligibility Cases
      1. *Ariosa Diagnostics, Inc.* v. *Sequenom, Inc*., (2021) FCAFC 101
      2. *Illumina, Inc.* v *Premaitha Health Plc* (2017) EWHC 2930 (Pat) Carr. J.
2. **§112 Issues with Monoclonal Antibodies**
   1. Background Reading on the Therapeutic Antibody Technology
      1. Lu, RM., Hwang, YC., Liu, IJ. *et al.* Development of therapeutic antibodies for the

treatment of diseases. *J Biomed Sci* **27,**1 (2020). <https://doi.org/10.1186/s12929-019-0592-z>

* + 1. Cabilly Patents – U.S. Patent Nos. 4,816,567 (Cabilly I) and 6,331,445 (Cabilly II)
  1. Cases
     1. ***Centocor Ortho Biotech, Inc. v. Abbott Labs*.,** 636 F.3d 1341 (Fed. Cir. 2011)
     2. *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014)
     3. *Amgen Inc. v. Sanofi*, 872 F. 3d 1367 (Fed. Cir. 2017)
     4. *Amgen Inc. v. Sanofi*,

1. **CRISPR**
   1. 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>

* 1. Cases

*Regents of the Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286 (Fed. Cir. 2018)

*Regents of the Univ. of Cal. v. Broad Inst., Inc.*, Patent Interference No. 106,115

**GUEST SPEAKERS**

1. **Richard Linn, Circuit Judge, United States Court of Appeals for the Federal Circuit**, has agreed to join the class for an afternoon to discuss the state of patent subject matter eligibility. <http://www.cafc.uscourts.gov/judges/richard-linn-circuit-judge>
2. ***Rachel Herder, J.D., Ph.D.,* Vice President of Intellectual Property, Mammoth Biosciences**, will join the class to discuss the state of CRISPR patents. Dr. Herder is the sole in-house attorney for Mammoth Biosciences, which is an early stage company co-founded by Nobel laureate Jennifer Doudna and is developing products based on the CRISPR platform.