

Biotechnology Law Fall 2023

Instructor Information

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Barbara McClung is Chief Legal Officer at Caribou Biosciences, Inc., a CRISPR genome-editing company located in Berkeley.

Matt Show is Biosciences IP Team Lead, Intellectual Property Counsel, at International Flavors & Fragrances (IFF), a global biotechnology company headquartered in New York City.

Course Information

Meetings: Tuesdays, 6:25 pm – 8:15 pm, with a 10-minute break
Location: Room 134
Prerequisites: Introductory patent or intellectual property course strongly recommended
Course number: 276.61 sec. 001
Credit Hours: 2 units

Office Hours

By appointment; instructors will stay after class for discussion and questions.

Course Description

This course will examine legal issues encountered uniquely and frequently in the biotechnology industry. Particular attention will be given to biotechnology-specific patent issues, intellectual property licensing, biotech patent prosecution considerations (U.S. and foreign), patent litigation, conducting due diligence in the biotech space, the regulatory landscape for pharmaceuticals and other biotech products, and various hot topics such as biotech patent cases pending before the U.S. Supreme Court and the CRISPR-Cas9 patent landscape. The course emphasis is on myriad real-life complexities faced by practitioners in the biosciences.

Course Materials

No textbook or reader will be assigned. Readings (e.g., cases, articles, statutes) will be posted on bCourses the week before.

bCourses

The class bCourse site is <https://bcourses.berkeley.edu/courses/1526416>. Reading materials for class, announcements, and the recording of each class after the scheduled class will be posted on the class bCourse site, which should be checked regularly by students.

Course-Specific Learning Outcomes

Students in Biotechnology Law will be expected to achieve the following Berkeley Law Learning Outcomes:

- (a) Identify and explain the rules and practical guidelines that legal professionals needed to practice in the biotechnology field;
- (b) Describe relevant areas of biotechnology law;
- (c) Analyze fact patterns faced by legal professionals in the biotechnology area and craft creative solutions to advise clients;
- (d) Understand and recommend approaches that biotechnology companies can take in various legal situations;
- (e) Opine on various biotechnology policy issues; and
- (f) Provide ethical legal counsel in the biotechnology law field.

Assignments and Final Exam

Performance will be evaluated on (1) a take-home final exam, and (2) two assignments.

Grading

The course grade will be calculated as follows:

- 70% final exam
- 30% two assignments (15% for each assignment)

Course Schedule

Class	Date	Topic
1	8/22	Practicing biotech law in the real world; refresher on patentability requirements, including 35 USC 101
2	8/29	Biotech-specific patent law considerations (35 USC 102, 103, 112)
3	9/5	Patent ownership
4	9/12	Patent licenses and negotiations Assignment #1 given
5	9/19	ASSIGNMENT #1 DUE In-class presentations
6	9/26	Creating a global patent portfolio Considerations for worldwide patent prosecution
7	10/3	Trade secret vs. patent considerations GMOs and the Nagoya Protocol
8	10/10	Terminal disclaimers; restriction practice; patent term adjustment (PTA); validity and freedom-to-operate opinions
9	10/17	Conducting and defending due diligence Assignment #2 given
10	10/24	ASSIGNMENT #2 DUE Regulatory process, patent term extension (PTE)
11	10/31	Hatch-Waxman litigation/settlements
12	11/7	Biosimilars litigation/settlements
13	11/14	Practicing law in a biotech company
14	11/21	CRISPR-Cas9: bringing it all together
15	12/5	Review session
	TBD	FINAL EXAM

School-wide Policies and Resources

(1) A “credit hour” at Berkeley Law is an amount of work that reasonably approximates three to four hours of work per week for 15 weeks, including a) classroom time, b) time spent preparing for class, c) time spent in review sessions and studying and taking, final exams, d) time spent researching, writing, and revising papers and other written work, and e) time spent preparing for and completing any other final project, presentation, or performance. For the purposes of these calculations, 50 minutes of classroom instruction counts as one hour, and the 15 weeks include the exam period. You can expect to spend this amount of time per unit per week on in-class and out-of-class, course-related work as described above. (Note that this total workload will be distributed differently in classes that only meet for part of the semester.)

(2) Students who need accommodations for disability or pregnancy or want to discuss the implementation of their accommodations, including accommodated exams, should contact [Chelsea Yuan](#), Director for Student Services, Accessible Education.

Student Services schedules all exams, including accommodated exams, as the law school is committed to anonymous grading. PROFESSORS DO NOT HAVE THE AUTHORITY TO RESCHEDULE EXAMS.

(3) The [Academic Honor Code](#) governs the conduct of all students during examinations and in all other academic and pre-professional activities at Berkeley Law. We expect students to adhere to this code scrupulously. If you have any questions about whether your conduct may violate the code, please contact your professor or the Dean of Students before you act. You may face severe consequences, including a failing grade in this class or removal from the program, and the Bar will receive notification of your conduct.

(4) [Berkeley Law Academic Skills Program](#). Every student admitted to Berkeley Law has the ability to succeed in law school and we are committed to fostering an academic environment in which all students can achieve their full potential. To schedule an individual appointment and for handouts on core law school skills and study strategies, free online study aids, information about practice exams and hypos, and much more, please visit and bookmark [the Academic Skills Program website](#).

(5) [Student Technology Help](#) As a Berkeley Law student, you are entitled to general software support for your computer from the law school, and certain free software downloads from UC Berkeley, while enrolled. If you have issues with internet access or computer equipment required to participate in classes remotely, contact studentcomputing@law.berkeley.edu. Information, links, and instructions for many common computer/technical questions can be found in the [law library's online computing guide](#). For bCourses, Zoom, and technical support questions, please email studentcomputing@law.berkeley.edu or you can use the [Student Computing chat](#). In both cases, someone will respond to you during our regular business hours.

If you have research-related questions, please contact the reference librarians by filling out the [reference request form](#). You can also reach reference librarians during business hours by using the [law library's chat service](#).

(6) If you are in need of economic, food, or housing support, you can find basic needs information [here](#). You may be eligible for money to buy groceries via [CalFresh](#) or our Food Assistance Program. If you need food immediately, please visit our [UC Berkeley Food Pantry](#).

(7) The University of California is committed to creating and maintaining a community dedicated to the advancement, application, and transmission of knowledge and creative endeavors through academic excellence, where all individuals who participate in University programs and activities can work and learn together in an atmosphere free of harassment, exploitation, or intimidation. Every member of the community should be aware that the University prohibits sexual violence and sexual harassment, retaliation, and other prohibited behavior (“Prohibited Conduct”) that violates the law and/or University policy. The University will respond promptly and effectively to reports of Prohibited Conduct and will take appropriate action to prevent, correct, and when necessary, to discipline behavior that violates this policy. For the complete UC Policy, definitions, compliance, and procedures, please access the [Sexual Violence and Sexual Harassment Policy](#).

Resources: If you have further questions or concerns about reporting behavior related to sexual harassment, sexual violence, and/or protected category discrimination, please contact the Office for the Prevention of Harassment and Discrimination (OPHD) by phone 510-643-7985 or email ask_ophd@berkeley.edu.

[Path to Care Center](#) Confidential Advocates provide affirming, empowering, and confidential support for those that have experienced gendered violence, including sexual harassment, emotional abuse, dating, and intimate partner violence, sexual assault, stalking, and sexual exploitation. Advocates bring a non-judgmental, caring approach to exploring all options, rights, and resources. They can be reached by phone at (510) 642-1988.