

Patent Law for Drug Development

REG 6260, Fall 2025

Thursdays, 5:00PM – 8:00PM
August 28 – December 4, 2025

Instructor Information

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Adjunct Professor

Course Coordinator: Layah Bogen

Texts and Reading Materials

Brougher, Joanna. *“Intellectual Property and Health Technologies: Balancing Innovation and the Public's Health”* Springer, 2014 Ed. (“IPHT”)

Brougher, Joanna. *“Billion Dollar Patents”* JTB Publishing, 2019 Ed. (“BDP”)

Selected materials containing the assigned, edited or excerpted portions of legal cases and articles will be available electronically on the course website.

Description

This course will examine the role and impact of patent law on the behavior of major players in the biotechnology and pharmaceutical industries as they navigate the regulatory process. This course begins with an overview of the current patent laws in the U.S. and how policies and recent changes to those laws affect the research and development of new medicines. This course will also examine the dilemmas created by patents as patent holders seek to bring their technology on to the market. The course will consist of synchronous and asynchronous materials and readings that will conclude with a paper and presentation analyzing a complex issue facing drug innovation and regulatory affairs.

Learning Objectives

Students completing this course will be able to:

1. Describe basic principles and processes of patent law and drug approval processes in the U.S.
2. Explain the roles of Congress, the courts, administrative agencies, and international law in regulating intellectual property as it relates to matters of drug development.
3. Analyze underlying conflicts in intellectual property law between stimulating innovation and navigating the regulatory process.
4. Critically evaluate the current intellectual property regime as a mechanism for spurring drug innovation, as well as proposals for alternative mechanisms for encouraging innovation.
5. Identify and critically analyze real-life situations involving intellectual property rights in drug development.

Outcome Measures

FINAL PAPER: Students will write a 5-7 page paper analyzing a topic of the student's choosing.

Grading Criteria

1. FINAL PAPER: The final paper will constitute 20% of the overall course grade. It will consist of the Final Paper Outline Presentation and the submission of the Final Paper.

2. DISCUSSION BOARDS: The six (6) discussion boards will each constitute 10% of the overall course grade for a total of 60%.

3. CLASS PARTICIPATION: Class participation consists of three elements: attendance, preparation, and thoughtful contribution to class discussions. Class participation will constitute 20% of the overall course grade.

Grading

The grading system is as follows: A, excellent; B, good; C, fair; D, poor; and F, failure.

LETTER GRADE	PERCENT SCORE
A	93-100
A-	90-92
B+	87-89
B	83-86
B-	80-82
C+	77-79
C	73-76
C-	70-72
D+	67-69
D	63-66
D-	60-62
F	0-59

At the graduate level for students enrolled in ITMAT Ed programs, **the minimum standard for satisfactory work in each course is a B-.**

ITMAT Education Learner's Guide

This guide aims to prepare you to engage meaningfully in ITMAT Ed courses. As an ITMAT Ed student, you may engage in both in-person and remote delivery methods. Remote course delivery can add flexibility for instructors and students by allowing for both synchronous interactions (live remote sessions) and asynchronous learning (out-of-class learning time used for studying resources, completing assignments, etc.).

If you have questions, feel free to reach out to your course coordinator, course director, and/or program director. If you have a circumstance or disability for which particular accommodations might be helpful, please check the [Weingarten Center Resources for Students in Online Programs](#) and contact program staff.

Community Standards and Program Expectations

Students must comply with the University's [Code of Student Conduct](#), [Code of Academic Integrity](#), and other University policies related to student conduct that appear in the [PennBook](#). These include, but are not limited to, policies on sexual harassment, acquaintance rape and sexual violence, appropriate use of electronic resources, open expression, and drug and alcohol usage. Students must comply with all [PSOM research policies](#), including but not limited to, policies on authorship. Additional codes of conduct and expectations students should be familiar with are the [equal opportunity and nondiscrimination statement](#), the [sexual misconduct policy and resource offices](#), and [student grievance procedures](#).

Synchronous Session Guidelines

- **Arrive Early.** Be on time; if online, make sure to log in to the virtual session a few minutes early to double-check your audio and video.
- **Be Respectful.** Be considerate and professional to the instructor and your peers. Avoid any behaviors that might be distracting to others.
- **Be an Active Participant.** Bring questions for instructors and classmates. During student presentations, actively engage with the content being presented by other students in the same way you would with an instructor.
- **Review Resources Ahead of Time.** Ensure you have a firm grasp on any content provided in advance of class and that you have followed instructions related to that content.
- **If online: Limit Noise.** Be in a quiet place, free of distractions or background noise. Keep yourself muted to reduce background noise, and then un-mute to ask questions or engage in discussion.
- **If online: Be Visible.** Have your video on during class. Be appropriately attired (casual wear is fine). It is important to the instructor and other students to feel engaged and attentive. If you need to step away to deal with a time-sensitive issue, you should turn off your video, send a message in the Zoom chat about needing to step away, and return as promptly as possible.
- **If online: Enable Live Transcription.** If captions would help you better understand or retain the conversation, [enable live transcription in Zoom. \(This is enabled on an individual basis\)](#)

Asynchronous Learning

- **Complete Assignments On Time.** Identify an effective method to keep track of assignments and due dates.
- **Engage with Peers.** Participate actively in discussion boards, group work, and other forums for peer communication.
- **Ask for Insight on Feedback.** If you have questions about feedback you received on an assignment, reach out to your course director.
- **Ask Questions as You Have Them.** Stay connected. Email your course director or program staff, ask for a phone call or meeting. Both program staff and course directors are happy to assist.

Canvas Best Practices

- **Turn on Notifications.** You can find your notification settings under “Account” on the top left menu. Please also ensure you’ve included your preferred email indicated through Account Settings and updated under “Ways to Contact” on the far right. Settings that will be most helpful to you are:
 - Announcement – Notify immediately (bell icon)
 - Grading – Notify immediately (bell icon)
- **Fill in Your Canvas Profile.** Adding a profile photo and your pronouns to your Canvas page lets your instructor and classmates get to know you better.
- **Use the course calendar and To-Dos.** The "Calendar" can help you keep track of due dates. Review the syllabus for important dates and transfer them into your personal calendar.
- **Check your browser compatibility.** Refer to the “**Policies, Procedures, and Technology**” page in your Canvas course to learn more about the browser and other technical information you need for Canvas. We recommend Chrome and Firefox's most up-to-date versions. (Safari has caused problems in the past.)

Program and Course Policies

Attendance

Students are allowed 1 excused absence. However, students are required to make up the content from the missed class. Beyond 1 excused absence, for every unexcused absence you will receive 2 points off your final, end-of-semester grade per additional absence.

If you will be absent, please contact the course director prior to your absence. If you have other concerns regarding attendance requirements, contact the course director as soon as possible.

Students need to be on time, in a location with guaranteed connectivity, keep their camera on, and remain engaged in class for the duration of the class. In the event of unavoidable circumstances that lead you to be late for class or need to leave early, please contact the course director at least one hour prior to class. Any student more than 15 minutes late or who does not keep video on will be considered absent from class. Additionally, any student who leaves early may be marked absent.

Students who are absent from any class are at a minimum always responsible for reviewing and other materials covered during a class. This may include recording, slides, assigned readings.

Participation Expectations

Participation in class is crucial to students' success in this program. Students are expected to attend and actively participate in all courses. To understand how to earn the full credit for participation, please see the examples and expectations below. For special circumstances, please email your course director.

Examples of active participation in a synchronous session include:

- asking or answering questions during class.
- posting comments in the chat.
- collaborating with other students during group work.
- incorporating knowledge or relevant experience to enrich the conversation.
- You are expected to speak up and/or include comments or reflections in the chat in the majority of synchronous classes to gain full participation points.
- Demonstrated knowledge of readings or session prep materials.

Examples of active participation in an asynchronous session include:

- commenting on discussion boards.
- completing short reflective assignments.
- applying information from asynchronous work to assignments and synchronous sessions.
- partnering with other students outside of synchronous class to conduct group assignments.
- Sharing.
- Demonstrated knowledge of readings or session prep materials.

This program is committed to creating a supportive, respectful, and productive learning environment for all students. Students will remain professional and respectful of their peers, course instructors, and guest lecturers. An important principal of code of conduct is to behave in the virtual space in the same way you would during an in-person class and/or a work meeting. **If you wouldn't do it in a work meeting or in-person class, don't do it in the virtual space.**

Academic Policies

General Attendance Guidelines

Attendance policies vary from course to course. Please see the course-specific policies regarding the number of acceptable excused absences and how to log absence excuses. Please note that the course director is not required to excuse multiple absences from students. If you are aware that you will not be able to attend multiple course sessions, you may be encouraged to seek a different course that is more suited to your schedule.

Incompletes

The mark of I is used to designate “incomplete”. A student who fails to complete a course and does not withdraw or change their status to auditor within the prescribed period shall receive, at the instructor’s discretion, either a grade of I (incomplete) or F (failure). When assigning an incomplete, the instructor may permit an extension of time up to one year for the completion of the course. Any course that is still incomplete after one calendar year from its official ending must remain as “incomplete” on the student’s record and shall not be credited toward a degree. If a student has 2 or more incompletes on their academic transcript, the student is ineligible to register for future courses and must meet with program leadership to develop a plan for how the incompletes will be resolved.

Code of Academic Integrity

The fundamental value of our academic community is intellectual honesty; accordingly, our academic community relies upon the integrity of every member. Students are responsible not only for adhering to the highest standards of truth and honesty but also for upholding the principles and spirit of the Academic Code. Violations of the Code include but are not limited to plagiarism, cheating, and fabrication, among others.

If you have questions regarding what is considered a violation of academic integrity, please review [The Code of Academic Integrity](#) in the PennBook.

Alleged violations of the Code of Academic Integrity are reviewed by the Program Director and as necessary, referred to the Penn Office of Student Conduct. If a student is unsure whether their action(s) constitute a violation of the Code of Academic Integrity, it is that student’s responsibility to consult with the instructor to clarify any ambiguities.

Use of Generative AI

It is plagiarism to submit work produced by a generative artificial intelligence (AI) service as your own without citing the source.

Students with Disabilities

The University of Pennsylvania provides reasonable accommodations to students with disabilities who have self-identified and been approved by the Office of Student Disabilities Services (SDS). Please make an appointment to meet with your instructor and the course coordinator as soon as possible to discuss your accommodations and your needs. To request accommodations or ask questions, you can make an appointment by calling SDS at 215-573-9235 or accessing the [MyWeingartenCenter](#) portal. The office is in the Weingarten Learning Resources Center at Hamilton Village, 220 S 40th St Suite 260. All services are confidential.

Learn more about the [types of services and accommodations offered by Weingarten](#).

Religious & Cultural Holidays

Religious and cultural holidays are listed on the [University of Pennsylvania's Chaplain website](#). If a student observes any of the listed holidays and they conflict with a class date, please contact program staff with the class date with which the holiday coincides. If an assignment is due during a holiday, program staff and faculty will work with the student to determine an alternative due date.

Suspension of Normal Operations Policy

In line with the university's [Suspension of Normal Operations Policy](#), when the University of Pennsylvania closes, synchronous classes will not be held. Assignments due on days impacted by a “suspension of normal operations” will be extended. In the case that a student is not located near Philadelphia and is experiencing a severe weather event, students should communicate with the Course Director and Course Coordinator to determine accommodations.

Course Evaluations

Course evaluations are an opportunity to share feedback on the strengths of the course, and opportunities for improvement. We welcome constructive feedback in the BLUE system. Completing evaluations is a required part of course participation. An email from the BLUE system is sent to students with a link and directions on how to complete the course evaluation(s). The program will release the grades once students submit their course evaluations.

Course Management: Canvas

All course materials and assignments will be managed on [Canvas](#). Log in with PennKey and password. Additional information on configuring and using Canvas will be provided in the Canvas site.

Class Schedule and Readings

Wk	Date	Topic	Concepts	Assignment(s) Due
0				Obtain the books.
1	08/28	Overview of Intellectual Property Law	An introduction to the U.S. intellectual property system, with a focus on the USPTO's role in examining and granting patents. Covers the fundamental requirements for obtaining patent protection and the common challenges applicants face.	Read: - IPHT, Chapt. 1 - BDP, Chapt. 1
2	09/04	Subject Matter Patentability: Genes and Medical Treatments	An in-depth exploration of patentable subject matter in the life sciences, including genetic material, diagnostic methods, and therapeutic treatments. Discusses the evolving legal standards and policy debates surrounding these areas.	Read: IPHT, Chapt. 3 & 4 *See Subj. Matter Note below. Sequenom Discussion due 9/10
3	09/11	Anticipation and Obviousness	A detailed look at the doctrines of anticipation (§102) and obviousness (§103) and how they impact the validity of pharmaceutical and biotech patents.	Read: - IPHT, Chapt. 2 - BDP, Chapt. 2 & 3 *See Anticipation Note below.
4	09/18	Written Description	An analysis of §112's written description and enablement requirements, with emphasis on recent court decisions shaping drug and biologic patent drafting strategies. Examines how these standards influence claim scope and enforceability.	Read: - IPHT, Chapt(s) 2 & 5 *See Written Description Note below. Jurassic Park Discussion due 09/24

*** Subj. Matter Note:**

35 U.S.C. § 101

Diamond v. Chakrabarty, 447 U.S. 303 (1980).

President & Fellows of Harvard College v. Canada (Commissioner of Patents)

Association for Molecular Pathology et al., v. Myriad Genetics, Inc., 569 U.S. ____ (2013).

Prometheus Laboratories, Inc. v. Mayo Collaborative Services, 566 U.S. ____ (2012)

Ariosa Diagnostics Inc. v. Sequenom Inc., 788 F.3d 1371

*** Anticipation Note:**

35 U.S.C. § 102 and § 103

Amarin Pharma, Inc. v. Hikma Pharma. USA Inc., 578 F. Supp. 3d 642 (D. Nev. 2022)

Juno Therapeutics, Inc. v. Kite Pharma, Inc. (Fed. Cir. 2021)

*** Written Description Note:**

35 U.S.C. § 112

University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997)

Amgen v. Sanofi, 872 F.3d 1367 (Fed. Cir. 2017)

In re Xencor, Appeal 2022-001944 (P.T.A.B. Jun. 1, 2023)

Wk	Date	Topic	Concepts	Assignment(s)
5	09/25	Patent Term and Exclusivity	An overview of how drugs progress from development to market, the FDA approval process, and the range of exclusivity incentives available to innovators. Also covers terminal disclaimers and their impact on patent term.	Read: - IPHT, Chapt. 6 - BDP, Chapt. 7 *See Patent Term and Exclusivity Note below.
6	10/02	Post-Grant Proceedings	Examines litigation strategies and post-grant proceedings, including inter partes review (IPR) and post-grant review (PGR), and their effect on life sciences patent enforcement. Discusses the balance between challenging invalid patents and protecting innovation.	Read: - IPHT, Chaps. 2 & 5 - BDP, Chaps. 2 & 3 *See Post-Grant Note below Final Project Topic Submission due 10/15
7	10/09	No Class – Fall Break		
8	10/16	Patent Battles 1: Hatch Waxman Act	Explains the legal and regulatory framework governing small-molecule drug patent disputes under the Hatch-Waxman Act, including Paragraph IV challenges, ANDA litigation, and strategic considerations for both brand and generic companies.	Read: - IPHT, Chapt. 7 *See Patent Battles 1 Note below
9	10/23	Patent Battles 2: BPCIA	Covers the Biologics Price Competition and Innovation Act (BPCIA) framework for biosimilar entry. Discusses the “patent dance,” exclusivity periods, and common litigation strategies used in biologics patent disputes.	Read: - IPHT, Chapt. 7 *See Patent Battles 2 Note below Patent Battles Discussion due 10/29
10	10/30		Analyzes how Orange Book listings, use codes, and related FDA processes	Read: - IPHT, Chapt. 7

		Orange Book Listings and FDA Interplay	interact with patent strategy. Explores strategies for building strong patent portfolios and how to align Orange Book listings with lifecycle management goals. Examines recent FTC actions challenging allegedly improper Orange Book listings and the broader regulatory push for transparency and competition.	*See Orange Book Note below
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*** Patent Term and Exclusivity Note:**

Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, J. Health Econ. 20, 31 (2016).

Joseph A. DiMasi & Henry G. Grabowski, The Cost of Biopharmaceutical R&D: Is Biotech Different? Managerial & Decision Econ. 469, 475 (2007).

Gilead Sciences, Inc. v. Natco Pharma Ltd., 753 F.3d 1208 (Fed. Cir. 2014)

In re Collect, LLC, 81 F.4th 1216 (Fed. Cir. 2023).

*** Post-Grant Note:**

Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 584 U.S. 275 (2018)

*** Patent Battles 1:**

Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005)

GSK v. Teva, 2018-1976 (2020)

Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc., 578 F. Supp. 3d 642 (D. Nev. 2022)

*** Patent Battles 2:**

Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664 (2017)

Amgen Inc. v. Sandoz Inc., 794 F.3d 1347 (Fed. Cir. 2015)

***Orange Book Note:**

Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, 60 F.4th 1373 (Fed. Cir. 2023)

Teva Pharms. USA, Inc. v. Amneal Pharms., LLC, No. 1:14-cv-00103 (D. Del.)

Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399 (2012)

H. Lundbeck A/S et al. v. Lupin Ltd. et al., No. 2022-1194, 2023 WL 8462010 (Fed. Cir. Dec. 7, 2023)

Wk	Date	Topic	Concepts	Assignment(s)
11	11/06	Pharmaceuticals & Antitrust	Explores antitrust issues in the pharmaceutical sector, including pay-for-delay settlements, product hopping, improper Orange Book listings, REMS abuses, citizen petitions, and pricing strategies. Evaluates the FTC's role in promoting competition.	Read: - IPHT, Chapt. 7 - BDP, Chapt. 8 *See Pharma/ Antitrust Note below. Pharma & Antitrust Discussion due 11/12
12	11/13	IP Ownership & Inventorship	Examines the allocation of rights between inventors, employers, and institutions. Covers contractual provisions and disputes arising from misaligned inventorship and ownership claims.	Read: IPHT, Chapter 5 *See Ownership & Inventorship Note below. Module Quiz: Scenarios in Ownership & Inventorship due 11/19

13	11/20	Global IP: Public Health and Access	Considers the intersection of patent rights and public health, including COVID-19 IP disputes, compulsory licensing, TRIPS flexibilities, march-in rights, and alternative incentive models. Analyzes global efforts to balance innovation with equitable access.	Read: - IPHT, Chapt. 5 - IPHT, Chapt. 9 *See Global IP Note below. Discussion Board due 12/03
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*** Pharma/ Antitrust Note:**

FTC v. Actavis, Inc., 570 U.S. ___, 133 S. Ct. 2223 (2013)

*** Ownership & Inventorship Note:**

Burroughs Wellcome Co. v. Barr Laboratories, Inc., 40 F. 3d 1223 (1994)

Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd., 964 F.3d 1365 (Fed. Cir. 2020)

*** Global IP Note:**

Bayh-Dole codified in 35 U.S.C. § 200-212, Available at

http://www.law.cornell.edu/uscode/html/uscode35/usc_sup_01_35_10_II_20_18.html

In the Case of NORVIR

In the Case of Xalatan

Wk	Date	Topic	Concepts	Assignment(s)
14	11/27	Thanksgiving Break	No Class	
15	12/04	Emerging Issues: Artificial Intelligence and Digital Health	Discusses the challenges of applying existing patent law to AI-generated inventions and digital health technologies. Examines USPTO guidance, recent court decisions, and the potential future direction of IP protection in these fields.	*See Emerging Issues Note below. Final Paper Due 12/17

*** Emerging Issues Note:**

Thaler v. Vidal, Fed. Cir. 2022

Commentary – AI is Breaking Patent Law (Nature)

USPTO – Comment – Genentech

USPTO – Tracing the Diffusion of AI with U.S. Patents