Patent Law for Drug Development

REG 6260, Fall 2024

Wednesdays, 5:00 – 8:00pm
August 28 – December 4, 2024

Instructor Information

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Adjunct Professor

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.

*syllabus is subject to change at professor's discretion

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.

Participation Expectations

Participation in class is crucial to students' education in this program. Students are expected to attend and actively participate in all courses. Examples of active participation in a synchronous session may include asking or answering questions, posting comments in the chat, or collaborating with other students during group work. Examples of active participation in an asynchronous session may include asking or answering questions via Canvas or email, commenting on discussion boards, or interacting with other students outside of class.

This program is committed to providing a supportive and productive learning environment for all. Active participation requires professionalism and demonstration of respect for peers, course instructors, and guest lecturers.

Attendance Expectations

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 coordinator prior to your absence. If you have other concerns regarding attendance requirements, contact the course coordinator 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 course coordinator and course director prior to class at least one hour prior to. 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 the class recording and other materials covered during a synchronous class.

<u>Synchronous Class Participation and Active Participation</u>

Participation in class is crucial to students' success. Students will attend and actively engage with the content and participate in discussion all courses. There are ten synchronous sessions for this course. To understand how to earn the full credit for participation below, please see the examples and expectations below. For special circumstances, please email your course coordinator.

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.**

We expect you to:

- Refer to "Community Standards and Program Expectations" for details on creating a quiet, distraction free environment.
- Keep your video on.
- Be appropriately attired (casual wear is fine).
- Approach debates and disagreements in a thoughtful and respectful manner.

If you have questions regarding appropriate behavior in a synchronous class, contact the course director.

Class Schedule and Readings

Wk	Date	Topic	Concepts	Assignment(s) Due
0				Obtain the books.
1	**08/28**	**Overview of Intellectual Property Law**	Understanding the role of the United States Patent & Trademark Office in regulating intellectual property; understanding the requirements and hurdles to obtaining patent protection.	**Read:** - IPHT, Chapt.1 - BDP, Chapt. 1
2	**09/04**	**Subject Matter Patentability: Genes and Medical Treatments**	Discussing the patenting of genetic research, medical treatments, and the debate surrounding them.	**Read:** IPHT, Chapt. 3 & 4 ***See Subj. Matter Note below.** **Sequenom Discussion** due 9/10
3	**09/11**	**Drug Development Processes – Naren Chirmule**	A case study of how drugs come to market	
4	**09/18**	**Anticipation and Obviousness**	Discussing inherency and obviousness and how their roles in obtaining and defending patents; case study involving Vascepta	**Read:** - IPHT, Chapt. 2 - BDP, Chapt. 2 & 3 ***See Anticipation Note below.**

*** 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)
Alice Corp. v. CLS Bank International, 573 U.S. __, 134 S. Ct. 2347 (2014)
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. 2:16-cv-02525-MMD-NJK
Juno Therapeutics, Inc. v. Kite Pharma, Inc. (Fed. Cir. 2021)

Wk	Date	Topic	Concepts	Assignment(s)
5	**09/25**	**Written Description**	Examining recent changes in Section 112 and their impact on patenting drug innovations.	**Read:** - IPHT, Chapt(s) 2 & 5 ***See Written Description Note below.** **Jurassic Park Discussion** due 10/1

6	**10/02**	**Patent Enforcement & Post Grant Proceedings**	Overview of patent litigation and enforcement options; examining recent changes in post grant proceedings and their impact on health technologies.	**Read:** - IPHT, Chapts. 2 & 5 - BDP, Chapts. 2 & 3 **Final Project Topic Submission** due 10/15
7	**10/16**	**Artificial Intelligence**	Discussing the new and growing field of artificial intelligence and how U.S. patent law is learning to accommodate this new area of innovation.	Read ***See AI Note below.** **AI Discussion** 10/22
8	**10/23**	**Drug Development and FDA Regulatory Processes**	Understanding how drugs come to market, including a look at navigating the FDA regulatory process, and market exclusivity-based incentives for drug development; overview of terminal disclaimers.	**Read:** - IPHT, Chapt. 6 - BDP, Chapt. 7 ***See Drug Dev. & FDA Reg. Processes Note below.**
9	**10/30**	**Patent Battles: Brand-Name Drugs vs. Generics**	How the patent regime stimulates and mediates battles between brand-name drug and generics—for example, through the Hatch Waxman Act.	Read: - IPHT, Chapt. 7 ***See Patent Battles 1 Note below**

*** 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)

Immunex Corp v. Sandoz 2:16-cv-01118-CCC-MF

*** AI 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

*** Drug Dev. &FDA Reg. Processes 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).

*** Patent Battles 1:**

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

GSK v. Teva, 2018-1976 (2020)

Wk	Date	Topic	Concepts	Assignment(s)
10	**11/06**	**Patent Battles: Brand-Name Biologics vs. Biosimilars**	How the patent regime stimulates and mediates battles between brand-name biologics and biosimilars through the BPCIA; examining strategies used in biotech and pharma to extend the market exclusivity of a product.	Read: - IPHT, Chapt. 8 - BDP, Chapt. 5 ***See Patent Battles 2 Note below.**
11	**11/13**	**Pharmaceuticals & Antitrust**	Examining antitrust issues in biotech and pharma, particularly issues surrounding settlements, OB listings, product hopping, REMS, citizens petitions, and price bundling and discounts.	Read - IPHT, Chapt. 7 - BDP, Chapt. 8 ***See Pharma/ Antitrust Note below.** **Pharma & Antitrust Discussion** due 11/19
12	**11/20**	**Ownership and Inventorship**	Examining inventorship v. ownership issues.	Read: IPHT, Chapter 5 ***See Ownership & Inventorship Note below.** **Discussion** due 11/27

*** Patent Battles 2 Note:**
Sandoz Inc. v. Amgen Inc., Supreme Court 2017
*** Pharma/ Antitrust Note:**
Burroughs Wellcome Co. v. Barr Laboratories, Inc., 40 F. 3d 1223 (1994)
*** Ownership & Inventorship Note:**
FTC v. Actavis, Inc., 570 U.S. ___, 133 S. Ct. 2223 (2013)
Antitrust Framework
Antitrust Overview

Wk	Date	Topic	Concepts	Assignment(s)
13	**11/27**	**Thanksgiving Break**	No Class Nov. 26	
14	**12/04**	**March-In Rights and Compulsory Licensing**	Understanding the role of patents and other factors that impact access to medicines; understanding the issues surrounding COVID-19 patent issues in the pandemic; examining march-in rights, compulsory licensing, patent waivers and alternative patent schemes.	Read: - IPHT, Chapt. 5 - IPHT, Chapt. 9 ***See Rights & Roles Gov't Note below.** **Discussion Board** due 12/10 **Final Paper Due 12/17**

*** Rights & Roles Gov't 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