Patent and Trade Secret Law

HLTH 7500

Course Description

This course provides an overview of the basic doctrines of patent law, as well as some related rights, including trade secrets and drug law exclusivity under the Hatch-Waxman Act. The course is intended for both individuals who work in fields related to intellectual property law and those with a more general interest in the topic. No specialized scientific knowledge is required. The course will focus on both substantive legal issues and the development of legal research and writing skills.

Readings

All readings for this course are available in a custom-made textbook published by Academic Pub.

Weekly Schedule

Week	Topic
1-3	Patent Protection Basics
4-5	Patent Infringement
6	Trade Secrets
7-8	Pharmaceutical Patents

Course Outcomes

Upon completion of the course, students will be able to:

CO 1. Explain the policies underlying patent law, trade secrets, and the Hatch-Waxman Act.
CO 2. Identify the basic workings of the patent system, specifically prosecution and litigation.
CO 3. Analyze the relationship between patent law and trade secrets.
CO 4. Analyze the workings of the Hatch-Waxman Act and the regulation of generic drug entry.
CO 5. Identify the use of patent law, trade secrets, and the Hatch Waxman Act as legal tools for developing and commercializing pharmaceutical inventions.
CO 6. Evaluate the role of competition law in interpreting and applying patent law, trade secrets, and the Hatch-Waxman Act.
CO 7. Assess ongoing controversies affecting the development of patent law and the pharmaceutical market.

Overview of Course Activities

Activity #1: Tutorial Questions

The Tutorial Questions are weekly assignments designed to ensure that you have an accurate understanding of the key points in the readings. Answers to these questions can be any length. Your goal should be to accurately state the relevant points of law as concisely as possible. Your professor will provide feedback and guidance on your responses. **Answers are due by 11:59PM on Wednesday.**

Tutorial Questions for week 1 are available with the first week's assignments. Tutorial Questions for the remaining weeks of the course are available on the Blackboard course site.

Activity #2: Discussion Questions

A "threaded discussion" is a discussion forum that allows students to respond to questions posted by the professor (original responses), which can then be read by other users who add their own comments in response (secondary postings). Unlike chat rooms and other "real-time" interaction forums, threaded discussions do not require different users to be logged on at the same time.

Discussion questions are assigned each week. **Original responses to these questions must be posted by Thursday at 11:59PM.** Original responses must be at least **250 words** and must incorporate concepts from the lectures and assigned readings.

Secondary Responses/Postings: Each student must post **two or more** secondary responses to other students' postings **for each discussion question**. Secondary responses are due by **11:59PM on the Monday following the week in which the questions were assigned.** They must be a minimum of **150 words** and, like original responses, should incorporate concepts from the lectures and assigned readings. Students are encouraged to embark on interactive discussions that go beyond the minimum number of secondary postings.

Although the discussion board is expected to be student-driven, professors will be participating in the discussions as well.

Discussion Questions for week 1 are available with the first week's assignments. Discussion Questions for the remaining weeks of the course are available on the Blackboard course site.

Activity #3 – Is It Patentable?

This activity is due on Saturday of Week 3. Further information is available on the Blackboard course site.

Activity #4 – Responding to an Infringement Claim

This activity is due on Saturday of Week 5. Further information is available on the Blackboard course site.

Activity #5 – Patents versus Trade Secrets

This activity is due on Saturday of Week 6. Further information is available on the Blackboard course site.

Activity #6 – Obtaining FDA Approval for a Generic Drug

This activity is due on Saturday of Week 8. Further information is available on the Blackboard course site.

Grading

ACTIVITIES	% OF FINAL GRADE
Activity #1: Tutorial Questions	25%
Activity #2: Discussion Questions	25%
Activity #3: Is It Patentable?	12.5%
Activity #4: Responding to an Infringement Claim	12.5%
Activity #5: Patents versus Trade Secrets	12.5%
Activity #6: Obtaining FDA Approval for a Generic Drug	12.5%

Responses to the Tutorial Questions and Discussion Questions will be graded each week in which they are assigned. At the end of the course, the lowest grade you receive for the Tutorial Questions and for the Discussion Questions will be dropped and will not be counted towards your final grade for the course. The purpose of this policy is to accommodate unanticipated professional or personal scheduling conflicts that may arise during the course.

IMPORTANT: **You are required to post a *minimum* of one 250-word main post plus two 150-word secondary posts to each weekly discussion thread/topic. Your weekly discussion board grade will be based upon the quantity and overall quality of your postings.**

Late Activities: For purposes of grading, activities and assignments that are submitted late will be treated as not having been submitted at all. The professor may make exceptions to this policy for true emergencies, such as serious illness. Requests for exceptions should be made in advance of the deadline, if possible. The professor's decision to grant or deny a request for an exception is final and unreviewable.

The following grade scale will be used to calculate final grades. The following is an explanation of how points equate to grades, based on a 4.33-point scale:

Grade	Quantitative	Qualitative	Definition
A+ A A-	4.33 4.00 3.67	Excellent	Superior understanding of the content and method of the course, extraordinary ability to recognize relationships between concepts, initiative in doing work in which quality consistently surpasses that required.
B+ B	3.33 3.00	Good	Good understanding of the content and method of the course, demonstrated ability to recognize relationships between concepts, substantial achievement of course objectives and fulfillment of course requirements.
B- C+ C	2.67 2.33 2.00	Fair	Rudimentary understanding of the content and method of the course, limited recognition of relationships between concepts, basic but incomplete achievement of course objectives and requirements.
C- D+ D	1.67 1.33 1.00	Unsatisfactory	Little understanding of the content and method of the course, inability to demonstrate minimum recognition of relationships between concepts, unsatisfactory achievement of course objectives and requirements.
F	0.00	Failure	Lack of understanding of the content and method of the course, failure to achieve objectives and/or complete requirements of the course.

Grades are based strictly on individual performance, not on any external factors (e.g., tuition reimbursement policies at your place of employment). Any questions about grades must be made in writing.