



ACADEMIC-GRADUATE STUDIES AND RESEARCH DIVISION

FIRST SEMESTER 2022-2023

Course Handout Part II

Date: 12-08-2023

In addition to part-I (General Handout for all courses appended to the time table) this portion gives further specific details regarding the course.

<i>Course No.</i>	: PHA G 545
<i>Course Title</i>	: IPR and Pharmaceuticals
<i>Instructor-in-Charge</i>	: P. YOGEE SWARI
<i>Instructor</i>	: Yuvaraj Singh

Course Description: Key aspects of intellectual property law and their impact on Pharmaceutical industry; concept of property with respect to intellectual creativity; emerging debates, policy issues and law reforms related to IPR with respect to pharmaceuticals; Issues of Intellectual Property such as Patents, Copyright, Trademarks, and Design; rules and regulations of marketing and competition; Patent processing, infringement of patents, ethics and economic issues related to IPR;

Scope and Objective of the Course:

This course considers key aspects of intellectual property law. It covers Indian legal system & its role in IPR. The course describes concept of property with respect to intellectual creativity. Attention will also be paid to emerging debates, policy issues and law reforms related to IPR with respect to pharmaceuticals. Issues of Intellectual Property such as Patents, Copyright, Trademarks, and Design will be brought up on the course, as well as rules and regulations of marketing and competition will be discussed. Patent processing, the acts which amount to infringement of patents, ethics and economic issues related to IPR will be discussed. The overall objective of this course is to equip students and stakeholders with knowledge of Intellectual Property Rights (IPR) related protection systems, their significance and use of IPR as a tool for wealth and value creation in a knowledge-based economy.

Learning Outcomes (course benefits): Students who have undergone the course will be able to-

-) Identify different types of Intellectual Properties (IPs), the right of ownership, scope of protection as well as the ways to create and to extract value from IP
-) Identify activities and constitute IP infringements and the remedies available to the IP owner and describe the precautions steps to be taken to prevent infringement of proprietary rights in pharma products.
-) Perform a patent search thoroughly with various tools both nationally and internationally
-) Draft a patent draft for an invention and create milestones with various deadlines for a national and international patent.
-) Assess a case on patent infringement
-) Understand the background of generic pharma manufacturing and the importance of patent expiry and ANDA filing to some extent.

Textbooks:

1. Bouchoux, D.E., Intellectual Property: The Law of Trademarks, Copyrights, Patents and Trade Secrets, Delmar Cengage Learning, New York, 4th edition, 2012.
2. Feroz Ali Khader, The Law of Patents – with a special Focus on Pharmaceuticals in India, LexisNexis Butterworths Wadhwa, Nagpur



Reference books

1. N.S. Gopalakrishnan & T.G. Agitha, Principles of Intellectual Property (2009), Eastern Book Company, Lucknow.
2. W.R. Cornish, Intellectual Property, Sweet & Maxwell, London(2000)
3. Class notes and study material provided

Course Plan:

Lecture No.	Learning objectives	Topics to be covered	Chapter in the Text Book
1	Scope, Objectives & IPR in pharmacy	Introduction	T2. Ch1
2-3	The Pharmaceutical Business	Understanding the pharmaceutical market	R3
4-5	Types of IPR and governing laws	Introduction to intellectual property law	R3
6-10	Foundation of law, selection and searching or trademark, registration process	Laws governing trademarks	T1. Ch 2-5
11-15	Foundation of law, registration process, subject matter of copyrights	Law of Copyrights	T1. Ch 9-15
16-17	Trade secret status and protection for submissions	Trade Secret Law	T1. Ch 22
18	Passing off, misappropriation	Unfair Competition	T1. Ch 23
19	Due Diligence and IPR audits	IPR Audits	T1. Ch 24
20-22	Foundation of patent Law	Patent Law	T1. Ch 17
23-26	Patent Search, Application and Post Issuance Proceedings		T1. Ch 18
27-30	Patent infringement and case studies		T1. Ch 20
31-33	Patent Ownership and Transfer		T1. Ch 19
34-35	New Development and International Patent Laws		T1. Ch 21
36-38	Patents in Pharmaceuticals	Hatch Waxman Act and acts of other countries specific to pharmaceuticals	R3
38-40	Compulsory Licensing	Compulsory Licensing	R3



Evaluation Scheme:

Component	Duration	Weightage (%)	Date & Time	Nature of Component
Pre-Mid term assignment	-	10	Will be announced in class	OB
Midterm test	90 min	35	12/10 - 4.00 - 5.30PM	CB
Assignments/seminars	-	15	Will be announced in class	OB
Comprehensive Exam	120 min	40	16/12 FN	OB

Mid-Semester Grading: Will be announced after midterm test.

Make-up: Prior approval or intimation to take a make-up is mandatory. It is solely at the discretion of the instructor-in-charge, depending upon the genuineness of the circumstances, to allow or disallow a student to appear for a make-up evaluation component. No makeup will be granted for Assignments/Quizzes under any circumstances.

Grading Procedure:

- Grading will be done by “bunching” procedure. Total marks obtained by the students will be arranged in descending order, ‘bunches’ will be identified and grades awarded accordingly. Fine grading system (A, A-, B, B-....) will be followed.
- It is not mandatory for the instructor-in-charge to award all the grades (A to E); subjective judgment will be used for awarding the grades.
- As specified in Handout – Part I, appended to the timetable, the instructor in-charge reserves the right to award a NC report in case the student does not make himself/ herself available for any of the evaluation component mentioned above.
- Borderline cases during grading will be judged on the basis of regularity to classes and consistency or progress in the performance in evaluation components.

Common Consultation Hour: To be announced in the class.

Notices: Notices pertaining to this course will be displayed in CMS portal and by email.

Academic Honesty and Integrity Policy: Academic honesty and integrity are to be maintained by all the students throughout the semester and no type of academic dishonesty is acceptable.

INSTRUCTOR-IN-CHARGE
PHA G545

