Roll No.												

PRESIDENCY UNIVERSITY

BENGALURU

Mid - Term Examinations – October 2025

Date: 07-10-2025 **Time:** 11.45am to 01.15pm

School: SOL	**Program:** BA,LLB/BBA,LLB/B.Com LLB (Hons)	
Course Code: LAW4082	**Course Name:** IPR in Pharma Industry	
Semester: VII	**Max Marks**:50	**Weightage**:25%

CO - Levels	**CO1**	**CO2**	**CO3**	**CO4**	**CO5**
Marks	**24**	**26**	**-**	**-**	**-**

Instructions:

(i) Read all questions carefully and answer accordingly.

(ii) Do not write anything on the question paper other than roll number.

Part A

Answer ALL the Questions. Each question carries 2marks. **5Q x 2M=10M**

1	Define a biotech patent with one example.	**2 Marks**	**L1**	**CO1**
2	Explain formulation patents with an illustration.	**2 Marks**	**L2**	**CO1**
3	List two features of the Patents (Amendment) Act, 2005.	**2 Marks**	**L1**	**CO2**
4	Describe briefly the concept of compulsory licensing in pharma.	**2 Marks**	**L2**	**CO2**
5	State two contributions of the Indian pharmaceutical industry to global healthcare.	**2 Marks**	**L1**	**CO2**

Part B

Answer the Questions. **Total Marks 40M**

6.	Sun Pharma develops a new antiviral molecule, "Sofivir," effective against resistant strains of Hepatitis C. Before filing a patent, the research team evaluates prior art, checks novelty, and ensures the molecule can be industrially produced. **Analyze the criteria for patentability of pharmaceutical**	**10 Marks**	**L3**	**CO1**

	inventions in India with reference to this case.			
	Or			
7.	Glenmark Pharmaceuticals modifies an existing anti-diabetic drug, "Glucorin," to improve solubility and patient compliance. They file a patent claiming enhanced therapeutic benefits. Patient advocacy groups argue that it is "evergreening," which involves merely extending monopoly rights without significant innovation under Section 3(d). **Evaluate whether this modification amounts to evergreening or a valid invention under Indian patent law.**	**10 Marks**	**L5**	**CO1**

8.	Biocon develops a combination therapy for Type 2 Diabetes, combining two existing drugs— **"**Metagliptin" and "Glucorin"—to improve efficacy and reduce side effects. The company files patents for both the composition and the manufacturing process. Patent examiners evaluate novelty, inventive step, industrial applicability, and unexpected therapeutic benefits. **Critically discuss the types of pharmaceutical patents in India and assess how this case fits within them.**	**10 Marks**	**L4**	**CO1**
	Or			
9.	Lupin Ltd. develops a new polymorphic form of "Azithral," a widely used antibiotic, claiming improved stability and shelf-life. Competitors argue the modification is minor and not a true invention. Regulators must assess novelty, inventive step, and industrial applicability before granting the patent, while considering the impact on generic competition. **Assess how polymorph and formulation patents are evaluated under Indian patent law using this example.**	**10 Marks**	**L3**	**CO1**

10.	After India complied with TRIPS and the 2005 Patents Amendment, Zydus Cadila faced challenges producing generic antiviral drugs for Hepatitis B, which were previously widely available and affordable. Multinational companies welcomed stricter product patent rules for protecting innovation, while patient advocacy groups raised concerns	**10 Marks**	**L4**	**CO2**

	about reduced access. Indian pharma had to adapt R&D strategies. **Analyze how TRIPS and the 2005 Patents Amendment reshaped the Indian pharmaceutical industry.**			
	Or			
11.	A life-saving leukemia drug, "Leucraz," is priced far beyond what most patients can afford. Civil society petitions the government, prompting the Controller of Patents to consider issuing a compulsory license. Indian law allows compulsory licensing when drugs are unaffordable, insufficiently available, or local manufacturing is lacking. **Examine the application of compulsory licensing in India with reference to this scenario**.	**10 Marks**	**L4**	**CO2**

12.	In Natco v. Bayer (2012), Bayer's cancer drug, Sorafenib, cost ₹2.8 lakh per month, which was unaffordable for most patients. Natco Pharma applied for a compulsory license to sell the drug at ₹8,800 per month, which was granted. In Novartis v. Union of India (2013), Novartis' patent application for an improved Imatinib (Glivec) was rejected under Section 3(d), preventing evergreening. **Critically analyze the principles established in these cases and explain how they shaped India's approach to innovation and evergreening.**	**10 Marks**	**L4**	**CO2**
	Or			
13.	A pharmaceutical company seeks a patent for a minor modification of a life-saving antiviral drug, "Virablock." Activists argue the change is trivial. Regulators examine whether the patent demonstrates a genuine inventive step or is an example of evergreening. Section 3(d) and compulsory licensing provisions help maintain access to medicines while encouraging real innovation. **Evaluate how Indian patent law prevents evergreening while encouraging genuine pharmaceutical innovation.**	**10 Marks**	**L5**	**CO2**