Roll No.												

PRESIDENCY UNIVERSITY

BENGALURU

End - Term Examinations – December 2025

Date: 09- 12-2025 **Time:** 01:00pm – 04:00pm

School: SOL-UG	**Program:** BA,LLB/BBA,LLB/B.Com LLB (Hons)	
Course Code: LAW4082	**Course Name**: IPR in Pharma Industry	
Semester: VII	**Max Marks**: 100	**Weightage**: 50%

CO - Levels	**CO1**	**CO2**	**CO3**	**CO4**	**CO5**
Marks	**14**	**24**	**24**	**19**	**19**

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. **10Q x 2M=20M**

1.	Define 'Biotech Patents' in the context of pharmaceuticals.	2 Marks	L1	CO1
2.	Explain the concept of 'Technical Advance' as a condition for patentability.	2 Marks	L2	CO1
3.	State the full form of GATT.	2 Marks	L1	CO2
4.	Explain the role of Section 3(d) of the Indian Patents Act in curbing Evergreening.	2 Marks	L2	CO2
5.	What is a Voluntary License?	2 Marks	L1	CO3
6.	Explain the grounds for a Compulsory License based on the patent not being worked in the territory of India.	2 Marks	L2	CO3
7.	What does TRIPS stand for?	2 Marks	L1	CO4
8.	Explain how the Patent Cooperation Treaty (PCT) benefits innovators.	2 Marks	L2	CO4
9.	Define the 'Right to Health' as recognized under the Indian Constitution.	2 Marks	L1	CO5
10.	Explain the relevance of the National Pharmaceutical Pricing Policy 2012 to the issue of ethical drug pricing.	2 Marks	L2	CO5

Part B

Answer the Questions. **Total Marks 80M**

11.		An inventor develops a new method for treating a disease using a patented drug. Analyze whether this new use/method can be granted a Technology Patent or if it falls under non-patentable subject matter.	10 Marks	L4	CO1
		Or			
12.		A major pharmaceutical company holds a patent for a drug compound, but an Indian generic firm successfully patents a new, more stable crystalline form (polymorph) of the same drug. Analyze the legal difference between Polymorph Patents and standard Drug Compound Patents under the Indian Patents Act, 1970.	10 Marks	L4	CO1
13.		India's Patent Law shifted from granting only process patents (pre-1995) to granting product patents (post-2005) for pharmaceuticals. Critically analyze the influence of the GATT and the subsequent TRIPS Agreement in compelling this fundamental change in India's Patent Law.	10 Marks	L4	CO2
		Or			
14.		A pharmaceutical company holds a patent for an anti-cancer drug and attempts to secure a new patent for a slightly improved, incremental version, extending its market monopoly. Analyze this scenario with specific reference to the Natco Case and the practice of Evergreening of Patents under Indian Patent Law.	10 Marks	L4	CO2
15.		A patent holder agrees to license its diabetes drug to a generic manufacturer at a negotiated royalty rate. Evaluate the mechanism of Voluntary License versus Compulsory License as tools for effectively promoting both innovation and public access to essential medicines.	10 Marks	L5	CO3
		Or			
16.		Following the Supreme Court's denial of a patent to Novartis for Gleevec, legal and pharmaceutical experts debated whether the ruling damaged India's reputation among foreign investors. Evaluate the long-term impact of the Novartis Case on foreign investment and domestic innovation in the Indian pharmaceutical sector.	10 Marks	L5	CO3
17.		The necessity of providing affordable anti-retroviral drugs in developing nations highlighted the conflict between global trade rules and public health. Evaluate the role of the Doha Declaration in providing a clear, pro-public health interpretation of the TRIPS Agreement.	15 Marks	L5	CO4
		Or			

18.		An Indian pharmaceutical company plans to file for patent protection for a new drug simultaneously in the USA, Europe, and Japan. Critically evaluate the framework of the Patent Cooperation Treaty (PCT) and assess its effectiveness in streamlining the global patent application process for pharmaceutical inventions, particularly from the perspective of developing country applicants.	15 Marks	L5	CO4

19.		The lack of affordable drugs during a major health crisis leads human rights activists to cite international obligations to health. Evaluate the arguments for and against patenting life-saving drugs from the perspective of both human rights obligations (specifically the ICESCR) and intellectual property rights.	15 Marks	L5	CO5
		Or			
20		The government imposes price caps on several essential patented drugs, citing the industry's ethical duty to ensure public health. Analyze the ethical responsibilities of the pharmaceutical industry in India, and evaluate the role of the National Pharmaceutical Pricing Policy 2012 in enforcing these responsibilities regarding drug affordability.	15 Marks	L5	CO5

21	**a.**	After the Patents (Amendment) Act 2005 introduced Product Patents, Indian companies could no longer freely manufacture generics of newly invented drugs. Analyze the primary challenges faced by the Indian pharma industry in adapting its business models and R&D strategies to this new regime.	10 Marks	L4	CO2
	b.	A patented HIV drug is sold in India at a price beyond the reach of 90% of the patient population, severely limiting treatment access. Analyze the legal grounds under which a Compulsory License could be issued for this product under Section 84 of the Indian Patents Act, 1970.	10 Marks	L4	CO3
		Or			
22	a.	A research firm develops a new diagnostic method based on an isolated but naturally occurring human gene sequence. Analyze the specific criteria for patenting Biotech Patents in India, focusing on the exclusions related to gene patents and diagnostic methods under the Patents Act, 1970.	10 Marks	L4	CO1
	b.	Prior to 2005, India did not grant product patents for pharmaceuticals, relying on process patents. Analyze the key provisions of the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) and explain how they fundamentally necessitated the implementation of the Product Patent system in India.	10 Marks	L4	CO4