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PRESIDENCY UNIVERSITY

Presidency University Act, 2013 of the Karnataka Act No. 41 of 2013 | Established under Section 2(f) of UGC Act, 1956
Approved by AICTE, New Delhi | Approved By BCI
Bengaluru

Even Semester End Term Examination, May / June 2026

Date: 25/05/2026

Time: 09.30 AM - 12.30 PM

Course Code: PGL3060

Course Name: Protection of Traditional Knowledge Plant Varieties and Biotechnology

Semester: Second Semester

Max. Marks: 100

Weightage: 50%

CO - Levels	CO1	CO2	CO3	CO4	CO5
Marks	34	30	42	32	42

PART A: Answer Following Questions. 20 M

Qn.No	Questions	M	CO	BT
1	Define "biotechnology" as understood in patent law and give one example.	2	CO2	BT1
2	What is the significance of the Basmati rice case in relation to Traditional Knowledge and geographical indications?	2	CO1	BT2
3	State the objectives of the CBD, 1992 in two sentences.	2	CO1	BT1
4	What are the three criteria for plant variety registration under the PPVFR Act?	2	CO2	BT1
5	What is meant by "compulsory licensing" under the PPVFR Act and when can it be granted?	2	CO4	BT1
6	Distinguish between "green biotechnology" and "white biotechnology" briefly.	2	CO2	BT1
7	What is the role of GEAC in the regulation of GM crops in India?	2	CO3	BT1
8	Name the two specific mechanisms of TK documentation discussed in class and state the full form of each.	2	CO2	BT1
9	What does Section 3(c) of the Patents Act, 1970 provide with reference to biotechnology?	2	CO5	BT1
10	State the ruling of Novartis v. Union of India (2013) in one sentence.	2	CO2	BT2

PART B: Answer Any 1 Following Questions. 10 M

Qn.No	Questions	M	CO	BT
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11	Explain how IP tools such as Geographical Indications and Trade Secrets can offer partial protection to Traditional Knowledge communities.	10	CO5	BT2
12	Explain the concept of collective ownership and community rights in the context of Traditional Knowledge with reference to legal frameworks.	10	CO5	BT2

PART C: Answer Any 1 Following Questions. 10 M

Qn.No	Questions	M	CO	BT
13	Discuss the meaning, legal status, and procedure for maintaining People's Biodiversity Registers under the Biological Diversity Act, 2002.	10	CO2	BT2
14	Explain the concept of Fair and Equitable Benefit Sharing (FEBS) under the Nagoya Protocol and the Biological Diversity Act with the help of the Divya Pharmacy case.	10	CO2	BT3

PART D: Answer Any 1 Following Questions. 10 M

Qn.No	Questions	M	CO	BT
15	Explain the meaning and implications of Section 3(d) of the Patents Act, 1970, with reference to Novartis v. Union of India (2013).	10	CO5	BT3
16	Discuss the rights of plant breeders under the PPVFR Act, 2001, and the limitations imposed by farmers' rights and compulsory licensing provisions.	10	CO5	BT2

PART E: Answer Any 1 Following Questions. 15 M

Qn.No	Questions	M	CO	BT
17	A local NGO from Kerala documents that an agricultural company has been selling improved varieties of a rice cultivar traditionally grown by farmers in the region, under a protected plant variety registration. The farmers claim the variety was based on seeds they had shared freely with researchers years ago. Discuss the grounds for cancellation of plant variety registration under the PPVFR Act, 2001 and the role of the PPVFR Authority.	15	CO1	BT4
18	Evaluate the legal and institutional significance of TKDL as an international defensive protection tool and assess whether India's current documentation mechanisms are adequate to prevent bio-piracy at the global level.	15	CO1	BT5

PART F: Answer Any 1 Following Questions. 15 M

Qn.No	Questions	M	CO	BT

19	A biotech company in Hyderabad has developed a new vaccine using a genetically modified virus vector. The vaccine underwent CDSCO approval. The company now applies for a patent. The Patent Office questions whether a vaccine using biological material qualifies for patent protection under Indian law. Examine the patentability of vaccines and genetically modified biological materials under Indian patent law, highlighting the relevant exclusions and regulatory concerns.	15	CO4	BT4
20	A tribal federation in Chhattisgarh discovers that a foreign university has filed patents in the USA based on genetic data collected from members of their community during a public health study. The community never gave explicit consent for commercial use of their genetic information. Critically analyze the role of the right to privacy and biodiversity laws in protecting indigenous communities from misuse of their genetic and traditional knowledge resources.	15	CO4	BT5

PART G: Answer Any 1 Following Questions. 20 M

Qn.No	Questions	M	CO	BT
21	A government report reveals that in the past decade, over 200 patents have been granted in foreign jurisdictions on formulations derived from traditional medicinal systems including Ayurveda, Siddha, and Unani. Most of these were granted because foreign patent offices were unaware of the prior art contained in ancient Indian texts. India's TKDL team has successfully challenged only 40 of these patents so far. The Ministry of Commerce is reviewing India's international IP strategy. Critically analyze India's framework for protection of Traditional Knowledge at the international level, highlighting its limitations.	20	CO3	BT5
22	An Indian pharmaceutical company develops a biosimilar version of a patented insulin product whose patent is about to expire. The original company argues that the biosimilar infringes its patent on the manufacturing process. The biosimilar company contends that the process was derived from publicly available scientific literature and does not meet the patentability threshold under Indian law. Meanwhile, patient groups demand affordable access to the biosimilar. Analyze the approach of Indian patent law towards biotechnological inventions and its impact on access to affordable medicines.	20	CO3	BT5