GUJARAT TECHNOLOGICAL UNIVERSITY

Program Name: Master of Science (Industrial Biotechnology)

Level: PG

Course / Subject Code: IB02001061

Course / Subject Name : Intellectual Property Rights, Biosafety and Bioethics

1. Learning Outcomes

Learning Outcome Component	Learning Outcome (Learner will be able to)
Theoretical and practical understanding of Intellectual Property Rights, Biosafety and Bioethics	• Analyze different types of intellectual property rights in general and protection of products derived from biotechnology research and issues related to application and obtaining patents. • Organize policy of companies and other technology-intensive organizations to build, manage and govern technology-based business.
Importance of Intellectual Property Rights, Biosafety and Bioethics	• Distinguish knowledge of biosafety and risk assessment of products derived from recombinant DNA research and environment release of genetically modified organisms, national and international regulations. • Analyze ethical aspects related to biological, biomedical, health care and biotechnology research.
Effective Communication	• Communicate concepts and ideas effectively.
Professional & Ethical Behaviour	• Transparency, honesty and ethical reasoning in handling animal cells as well as toxic, corrosive or mutagenic.

LO – PO Mapping: Correlation Levels:
1 = Slight (Low); 2 = Moderate (Medium); 3 = Substantial (High), "-"= no correlation

Sub Code: 1320106	PO1	PO2	PO3	PO4	PO5	PO6	PO7
LO1:Theoretical and practical understanding of Intellectual Property Rights, Biosafety and Bioethics	2	2	3	3	2	2	2
LO2:Importance of Intellectual Property Rights, Biosafety and Bioethics	2	3	3	2	2	3	2
LO3: Effective communication	2	3	2	2	3	3	2
LO4: Professional & Ethical Behaviour	3	2	3	3	2	2	3

Course Duration: The course duration is 30 sessions of 60 minutes each.

3. Course Contents:

Module No:	Module Content	No. of Sessions	70 Marks (External Evaluation)
1	**Introduction to IPR** Introduction to intellectual property; types of IP: patents, trademarks, copyright & related rights, industrial design, traditional knowledge, geographical indications, protection of new GMOs; International framework for the protection of IP; IP as a factor in R&D; IPs of relevance to biotechnology and few case studies; introduction to history of GATT, WTO, WIPO and TRIPS; plant variety protection and farmers rights act; concept of 'prior art': invention in context of "prior art"; patent databases - country-wise patent searches (USPTO, EPO, India); analysis and report formation.	5	14
2	**Patenting** Basics of patents: types of patents; Indian Patent Act 1970; recent amendments; WIPO Treaties; Budapest Treaty; Patent Cooperation Treaty (PCT) and implications; procedure for filing a PCT application; role of a Country Patent Office; filing of a patent application; precautions before patenting-disclosure/non-disclosure - patent application- forms and guidelines including those of National Bio-diversity Authority (NBA) and other regulatory bodies, fee structure, time frames; types of patent applications: provisional and complete specifications; PCT and conventional patent applications; International patenting-requirement, procedures and costs; financial assistance for patenting; introduction to existing schemes; publication of patents-gazette of India, status in Europe and US; patent infringement- meaning, scope, litigation, case studies and examples; commercialization of patented innovations; licensing –	6	14

	outright sale, licensing, royalty; patenting by research students and scientists-university/organizational rules in India and abroad, collaborative research - backward and forward IP; benefit/credit sharing among parties/community, commercial (financial) and non-commercial incentives.		
3	**Finance and accounting** Biosafety and Biosecurity - introduction; historical background; introduction to biological safety cabinets; primary containment for biohazards; biosafety levels; GRAS organisms, biosafety levels of specific microorganisms; recommended biosafety levels for infectious agents and infected animals; definition of GMOs & LMOs; principles of safety assessment of transgenic plants – sequential steps in risk assessment; concepts of familiarity and substantial equivalence; risk – environmental risk assessment and food and feed safety assessment; problem formulation – protection goals, compilation of relevant information, risk characterization and development of analysis plan; risk assessment of transgenic crops *vs* cisgenic plants or products derived from RNAi, genome editing tools.	8	14
4	**National and international regulations** International regulations – Cartagena protocol, OECD consensus documents and Codex Alimentarius; Indian regulations – EPA act and rules, guidance documents, regulatory framework – RCGM, GEAC, IBSC and other regulatory bodies; Draft bill of Biotechnology Regulatory authority of India - containments – biosafety levels and category of rDNA experiments; field trails – biosafety research trials – standard operating procedures - guidelines of state governments; GM labeling – Food Safety and Standards Authority of India (FSSAI).	5	14

5	**Bioethics** Introduction, ethical conflicts in biological sciences - interference with nature, bioethics in health care - patient confidentiality, informed consent, euthanasia, artificial reproductive technologies, prenatal diagnosis, genetic screening, gene therapy, transplantation; Bioethics in research – cloning and stem cell research, Human and animal experimentation, animal rights/welfare, Agricultural biotechnology - Genetically engineered food, environmental risk, labeling and public opinion; Sharing benefits and protecting future generations - Protection of environment and biodiversity – biopiracy.	6	14

4. Pedagogy:

- ICT enabled Classroom teaching
- Practical / live assignment
- Interactive classroom discussions

5. Evaluation:
Students shall be evaluated on the following components:

A	**Mid-Semester Examination**	**(Internal assessment-30 Marks)**
B	**End-Semester Examination**	**(External assessment-70 Marks)**

6. Reference Books:

No	Author	Name of the Book	Publisher	Year of Publication / Edition
1	Ganguli, P.	Intellectual Property Rights: Unleashing the Knowledge Economy.	Tata McGraw-Hill Pub	Latest Edition
2	Kuhse, H.	Bioethics: an Anthology	Blackwell	Latest Edition
3	Karen F. Greif and Jon F. Merz	Current Controversies in the Biological Sciences -Case Studies of Policy Challenges from New Technologies	MIT Press	Latest Edition

4	Wolt, J. D., Keese, P., Raybould, A., Fitzpatrick, J. W., Burachik, M., Gray, A., Wu, F.	Problem Formulation in the Environmental Risk Assessment for Genetically Modified Plants	Transgenic Research	Latest Edition
5	Craig, W., Tepfer, M., Degrassi, G., & Ripandelli, D.	An Overview of General Features of Risk Assessments of Genetically Modified Crops	Euphytica	Latest Edition

Note: Wherever the standard books are not available for the topic appropriate print and online resources, journals and books published by different authors may be prescribed.

7. List of Journals/Periodicals/Magazines/Newspapers / Web resources, etc

- https://ipindiaservices.gov.in/publicsearch/
- https://www.wipo.int/academy/en/courses/distance_learning/
- https://www.eubios.info/networks/all_india_bioethics_association

Course Outcomes:

On completion of this course, students should be able to:

- Understand the rationale for and against IPR and especially patents;
- Understand why India has adopted an IPR policy and be familiar with broad outline of patent regulations.
- Understand the different types of intellectual property rights in general and protection of products derived from biotechnology research and issues related to application and obtaining patents;
- Gain knowledge on biosafety and risk assessment of products derived from recombinant DNA research and environmental release of genetically modified organisms, national and international regulations;
- Understand ethical aspects related to biological, biomedical, health care and biotechnology research.