

GUJARAT TECHNOLOGICAL UNIVERSITY
Syllabus for M.Sc. in Industrial Biotechnology, Semester - 2
Subject Name: Intellectual Property Rights, Biosafety and Bioethics

Subject Code: 1320106

W.E.F 2021-22

1. Learning Outcomes

Learning Outcome Component	Learning Outcome (Learner will be able to)
Theoretical and practical understanding of Intellectual Property Rights, Biosafety and Bioethics	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Communicate concepts and ideas effectively.
Professional & Ethical Behaviour	<ul style="list-style-type: none"> 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

2. 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	<u>Introduction to IPR</u>	5	14

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	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.		
2	<p><u>Patenting</u></p> <p>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 – 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.</p>	6	14

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3	<p><u>Finance and accounting</u></p> <p>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.</p>	8	14
4	<p><u>National and international regulations</u></p> <p>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).</p>	5	14
5	<p><u>Bioethics</u></p> <p>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</p>	6	14

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	biotechnology - Genetically engineered food, environmental risk, labeling and public opinion; Sharing benefits and protecting future generations - Protection of environment and biodiversity – biopiracy.		
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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

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- <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.