

Name of the Programme: M.Sc. Marine Biotechnology

Course Code: MBT 621

Title of the Course: IPR, Biosafety & Bioethics

Number of Credits: 3

Effective from AY: 2022-23

Pre-requisites for the Course:	No prerequisite is required	
Course Objectives:	<ol style="list-style-type: none"> 1) To provide basic knowledge on intellectual property rights and their implications in biological research and product development; 2) To learn biosafety and risk assessment of products derived from biotechnology and regulation of such products; 3) To become familiar with ethical issues in biological research. 4) Understand the consequences of biomedical research technologies such as cloning of whole organisms, genetic modifications, DNA testing. 	
Content:	<p style="text-align: center;"><u>MODULE I</u></p> <ul style="list-style-type: none"> • Different types of IP: patents, trademarks, copyright, industrial design, traditional knowledge, geographical indications, Trade Secrets. • Basics of patents: types of patents; • Concept of 'prior art': invention in context of "prior art"; • Precautions before patenting-disclosure/non-disclosure • Patent application- forms and guidelines, fee structure, time frames; • Types of patent applications: provisional and complete specifications; • PCT and conventional patent applications; procedure for filing a PCT application; role of a Country Patent Office; filing of a patent application; • Patent databases - IP as a factor in R&D; IPs of relevance to biotechnology and few case studies; • WIPO Treaties; Budapest Treaty; Patent Cooperation 	<p>No. of hours</p> <p style="text-align: center;">15</p>

	<p>Treaty (PCT)</p> <ul style="list-style-type: none"> • International framework for the protection of IP • National Bio-diversity Authority (NBA) and other regulatory bodies, protection of new GMOs; • History of GATT, WTO, WIPO and TRIPS; plant variety protection and farmers rights act; • Country-wise patent searches (USPTO, EPO, India); analysis and report formation. • International patenting-requirement, procedures and costs; financial assistance for patenting • 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 style="text-align: center;"><u>MODULE II</u></p> <ul style="list-style-type: none"> • 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 	15

	<p>characterization and development of analysis plan; risk assessment of transgenic crops vs cisgenic plants or products derived from RNAi, genome editing tools.</p> <ul style="list-style-type: none"> • 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 style="text-align: center;"><u>MODULE III</u></p> <ul style="list-style-type: none"> • 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 	15
Pedagogy:	Lectures, tutorials, Case studies, assignments	
References/ Readings:	<ol style="list-style-type: none"> 1. L. Bently and B. Sherman, Intellectual property law . Oxford University Press, 2008. 2. L. Bently, Intellectual property law Oxford University Press., 2008. 	

3. Complete Reference to Intellectual Property Rights
4. T. M. Cook, A User's Guide to Patents Tottel Publishing., 2007.
5. W. Craig, M. Tepfer, G. Degrassi, & D. Ripandelli, An Overview of General divisions/csurv/geac/annex-5.pdf F, 2009.
6. Problem Formulation in the Environmental Risk Assessment for Genetically Modified Plants. Transgenic Research, 19(3), 425-436. doi:10.1007/s11248-009-9321-9
7. D. O. Fleming, D. L. Hunt, Biological safety: principles and practices ASM Press., 2000.
8. P. Ganguli, Intellectual Property Rights: Unleashing the Knowledge Economy. New Delhi: Tata McGraw-Hill Pub., 2001.
9. Grubb P. W. Grubb P. L. Thomsen, P. R., Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy Oxford University Press., 2010.
10. <http://www.wipo.int>
11. International Union for the Protection of New Varieties of Plants. <http://www.upov.int>
12. J. Rajmohan. Biosafety and bioethics Gyan Publishing House., 2006.
13. F. Karen . Greif and Jon F. Merz, Current Controversies in the Biological Sciences – Case Studies of Policy Challenges from New Technologies, MIT Press
14. Keith F, CRC handbook of laboratory safety. A.CRC Press.,2000.
15. H. Kuhse, Bioethics: An Anthology. Malden, MA: Blackwell., 2010.
16. Laws. Snow White Publication Oct., 2007.
17. National Biodiversity Authority. <http://www.nbaindia.org>
18. National IPR Policy, Department of Industrial Policy & Promotion, Ministry of Commerce, Gol.
19. National Portal of India.<http://www.archive.india.gov.in>
20. Office of the Controller General of Patents, Design & Trademarks; Department of Industrial Policy & Promotion; Ministry of Commerce & Industry; Government of India. <http://www.ipindia.nic.in/>
21. Recombinant DNA Safety Guidelines, Department of Biotechnology, Ministry of Science and Technology, Govt. of India, 2017. Retrieved from <https://dbtindia.gov.in/>
22. K. Singh. Intellectual property rights in Biotechnology. A status report New Delhi Biotech Consortium, India, 1993.
23. N.S. Sreenivasulu, and C.B. Raju, Biotechnology and Patent laws: patenting living beings Manupatra Publishers, 2008.
24. Wegner H. Patent law in Biotechnology, chemicals &

	<p>pharmaceuticals. Stockton Press, 1994.</p> <p>25. Wolt, J. D., Keese, P., Raybould, A., Fitzpatrick, J.W., Burachik, M., Gray, A., Wu, World Intellectual Property Organisation. World Health Organization. Laboratory biosafety manual. WHO press, 2004.</p> <p>26. World Trade Organisation. http://www.wto.org</p>
Course Outcomes:	<p>On completion of this course, students should be able to:</p> <ol style="list-style-type: none"> 1. understand the rationale for and against IPR and especially patents; 2. understand why India has adopted an IPR Policy and be familiar with broad outline of patent regulations; 3. understand different types of intellectual property rights 4. gain knowledge national and international regulations of biosafety and risk assessment of products derived from recombinant DNA research and environmental release of GMOs 5. describe the major competing ethical theories and apply ethical theory to contemporary moral issues that arise out of recent developments in the life sciences that affect public policy. 6. analyze and clarify moral beliefs about abortion, human reproduction, decisions of life and death, mental illness and other related issues.