Programme: M.Sc. Marine Biotechnology
Course Code: MBO 187
Title of the course: IPR, BIOSAFETY AND BIOETHICS
Number of credits: 2
Effective from: 2019-2020

Course Objectives	• To provide basic knowledge on intellectual property rights and their implications in biological research and product development; • To become familiar with India's IPR Policy; • To learn biosafety and risk assessment of products derived from biotechnology and regulation of such products; • To become familiar with ethical issues in biological research. This course will focus on consequences of biomedical research technologies such as cloning of whole organisms, genetic modifications, DNA testing	
Learning 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 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 of biosafety and risk assessment of products derived from recombinant DNA research and environmental release of genetically modified organisms, national and international regulations.	
Contents	**MODULE I** 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. 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;	12 hours

	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. **MODULE II** 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 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). 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.	12 hours
References/	1. A User's Guide to Patents (2007) Trevor M. Cook. Tottel Publishing.	

Reading	2. Biosafety and bioethics (2006) Rajmohan Joshi. Gyan Publishing House. 3. Biotechnology and Patent laws:patenting living beings (2008) Sreenivasulu, N.S. and Raju C.B. Manupatra Publishers. 4. *Complete Reference to Intellectual Property Rights Laws*. (2007). Snow White Publication Oct. 5. Craig, W., Tepfer, M., Degrassi, G., &Ripandelli, D. (2008). *An Overview of General* divisions/csurv/geac/annex-5.pdf 6. F. (2009). *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. *Features of Risk Assessments of Genetically Modified Crops*. Euphytica 8. Ganguli, P. (2001). *Intellectual Property Rights: Unleashing the Knowledge Economy*. New Delhi: Tata McGraw-Hill Pub. 9. Intellectual property law (2008) Lionel Bently, Brad Sherman. Oxford University Press. 10. International Union for the Protection of New Varieties of Plants. http://www.upov.int 11. Karen F. Greif and Jon F. Merz, *Current Controversies in the Biological Sciences - Case Studies of Policy Challenges from New Technologies*, MIT Press 12. Kuhse, H. (2010). *Bioethics: an Anthology*. Malden, MA: Blackwell. 13. National Biodiversity Authority. http://www.nbaindia.org 14. *National IPR Policy*, Department of Industrial Policy & Promotion, Ministry of Commerce GoI, National Portal of India. http://www.archive.india.gov.in 15. 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/ 16. Patents for Chemicals, Pharmaceuticals a nd Biotechnology:Fundamentals of Global Law, Practice and Strategy (2010) Grubb P. W. Grubb, P. L. Thomsen, P. R. Oxford University Press. 17. Recombinant DNA Safety Guidelines, 1990 Department of Biotechnology, Ministry of Science and Technology, Govt. of India. Retrieved from http://www.envfor.nic.in/ 18. Wolt, J. D., Keese, P., Raybould, A., Fitzpatrick, J. W., Burachik, M., Gray, A., Wu, World Intellectual Property Organisation. http://www.wipo.int 19. World Trade Organisation. http://www.wto.org	