# ELECTIVE COURSE IV-2; BIOSAFETY AND PATENT RIGHTS

# UNIT - I

**Biosafety:** Introduction; biosafety issues in biotechnology-historical background; Introduction to Biological Safety Cabinets; Primary Containment for Biohazards; Biosafety Levels; Biosafety Levels of Specific Microorganisms; Recommended Biosafety Levels for Infectious Agents and Infected Animals.

# UNIT -II

**Biosafety Guidelines**: Biosafety guidelines and regulations (National and International) – operation of biosafety guidelines and regulations of Government of India; Definition of GMOs & LMOs; Roles of Institutional Biosafety Committee, RCGM, GEAC etc. for GMO applications in food and agriculture; Environmental release of GMOs; Risk Analysis; Risk Assessment; Risk management and communication; Overview of National Regulations and relevant International Agreements including Cartegana Protocol.

### UNIT- III

**Introduction to Intellectual Property:** Types of IP: Patents, Trademarks, Copyright & Related Rights, Industrial Design, Traditional Knowledge, Geographical Indications- importance of IPR – patentable and non patentables – patenting life – legal protection of biotechnological inventions – world intellectual property rights organization (WIPO).

### UNIT- IV

**Basics of Patents and Concept of Prior Art:** Introduction to Patents; Types of patent applications: Ordinary, PCT, Conventional, Divisional and Patent of Addition; Specifications: Provisional and complete; Forms and fees Invention in context of "prior art"; Patent databases; Searching International Databases; Country-wise patent searches (USPTO, esp@cenet(EPO), PATENTScope(WIPO), IPO, etc.).

**Patent Filing Procedures:** National & PCT filing procedure; Time frame and cost; Status of the patent applications filed; Precautions while patenting – disclosure/non-disclosure; Financial assistance for patenting - introduction to existing schemes Patent licensing and agreement Patent infringement-meaning, scope, litigation, case studies.

### UNIT -V

**Agreements and Treaties:** History of GATT & TRIPS Agreement; Madrid Agreement; Hague Agreement; WIPO Treaties; Budapest Treaty; PCT; Indian Patent Act 1970 & recent amendments.

# **REFERENCES:**

- 1. M.W. and Schinzinger.R. 2003. Ethics in engineering, Martin III Edition, Tata McGraw-Hill, New Delhi.
- 2. BAREACT, 2007.Indian Patent Act 1970 Acts & Rules, Universal Law Publishing Co. Pvt. Ltd., New Delhi.
- 3. Kankanala C. ., 2007. Genetic Patent Law & Strategy, 1st Edition, Manupatra Information Solution Pvt. Ltd. New Delhi.
- 4. Jose Cibelli, Robert P. lanza, Keith H. S. Campbell. 2002. Michael D.West, Principles of Cloning, Academic Press,London.
- 5. B.B.Hosetti, B.B. 2002. Glimpses of Biodiversity. Daya, Delhi.
- 6. Senthil Kumar Sadhasivam and Mohammed Jaabir M. S. 2008. IPR, Biosafety and Biotechnology Management. Jasen Publications, Tiruchirappalli, India.
- 7. http://www.cbd.int/biosafety/background.shtml
- 8. http://web.princeton.edu/sites/ehs/biosafety/biosafetypage/section3.html