

MBT 201- IPR & BIOSAFETY

Module-I

Introduction to Intellectual Property

Types of IP: Patents, Trademarks, Copyright & Related Rights, Industrial Design, Traditional Knowledge, Geographical Indications, Protection of GMOs IP as a factor in R&D; IPs of relevance to Biotechnology

Module-II

Agreements and Treaties

History of GATT & TRIPS Agreement; Madrid Agreement; Hague Agreement; WIPO Treaties; Budapest Treaty; PCT; Indian Patent Act 2005 & recent amendments.

Module-III

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), PATENT Scope (WIPO), IPO, etc.)

Module-IV

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, Deliberate testing-Transgenic testing, Centers in India for Testing.

Module-V

Biosafety

Introduction; Principles of laboratory biosafety and biosecurity; Risk assessment: Occupational health hazards and laboratory associated infections (LAIs); Laboratory biosafety level criteria and biosafety laboratory design; Primary containment for biohazards: Selection, installation and used of biosafety cabinets; Decontamination and disinfection; Safe working practices in biorisk areas and waste management of biohazards; Biosafety guidelines - Government of India; Definition of GMOs & LMOs; Institutional Biosafety Committee (IBSC), Institutional Animal

Ethics Committee (IAEC), Review Committee for Genetically Modified organisms (RCGM), Genetic Engineering Approval Committee (GEAC) etc. for GMO applications in food and agriculture; Environmental release of GMOs. Handling and transportation of infectious material and genetically modified products.

Case studies.

Texts/References:

1. **BAREACT, Indian Patent Act 2005, Acts & Rules, Universal Law Publishing Co. Pvt. Ltd., 2007.**
2. **Kankanala C. Genetic Patent Law & Strategy, 1st Edition, Manupatra Information Solution Pvt. Ltd., 2007.**
3. **M. K. Sateesh I. K. International Pvt. Ltd. Bioethics and Biosafety, 2008.**
4. **Frederic H. Erbis, Karim M. Maredia. Intellectual property rights in agricultural biotechnology, CAB International publication, USA, New Edition.**
5. **Rajmohan Joshi. Biosafety and Bioethics, Gyan Publishing House, 2006.**
6. **Selected papers from scientific journals.**

Important Links:

1. <http://www.w3.org/IPR/>
2. <http://www.wipo.int/portal/index.html.en>
3. http://www.ipr.co.uk/IP_conventions/patent_cooperation_treaty.html
4. www.patentoffice.nic.in
5. www.iprlawindia.org/ - 31k - Cached - Similar page
6. <http://www.cbd.int/biosafety/background.shtml>
7. <http://www.cdc.gov/OD/ohs/symp5/jyrtext.htm>
8. <http://web.princeton.edu/sites/ehs/biosafety/biosafetypage/section3.html>

SEMESTER-II

MBT202-BIO-ENTREPRENEURSHIP

Module I

Accounting and Finance

Taking decision on starting a venture; Assessment of feasibility of a given venture/new venture; Approach a bank for a loan; Sources of financial assistance; Making a business proposal/Plan for seeking loans from financial institution and Banks; Funds from bank for capital expenditure and for working; Statutory and legal requirements for starting a company/venture; Budget planning and cash flow management; Basics in accounting practices: concepts of balance sheet, P&L account, and double entry bookkeeping; Estimation of income, expenditure, profit, income tax etc.

Module II

Marketing

Assessment of market demand for potential product (s) of interest; Market conditions, segments; Prediction of market changes; Identifying needs of customers including gaps in the market, packaging the product; Market linkages, branding issues; Developing distribution channels; Pricing/Policies/Competition; Promotion/Advertising; Services Marketing

Module III

Negotiations/Strategy

With financiers, bankers etc.; with government/law enforcement authorities; With companies/Institutions for technology transfer; Dispute resolution skills; External environment/changes; Crisis/ Avoiding/Managing; Broader vision–Global thinking

Module IV

Information Technology

How to use IT for business administration; Use of IT in improving business performance; Available software for better financial management; E-business setup, management.

Human Resource Development (HRD)

Leadership skills; Managerial skills; Organization structure, pros & cons of different structures; Team building, teamwork; Appraisal; Rewards in small scale set up.

Fundamentals of Entrepreneurship

Support mechanism for entrepreneurship in India

Module V

Role of knowledge centre and R&D

Knowledge centres like universities and research institutions; Role of technology and up gradation; Assessment of scale of development of Technology; Managing Technology Transfer; Regulations for transfer of foreign technologies; Technology transfer agencies.

Case studies.

Industrial Training:

Texts/References:

1. Shkula. S. M. Advanced Accountancy, Masherwari, Sahitya Bhawan, Agra.
2. Kotler. P. Marketing Management, Prentice Hall of India Limited.
3. Staton. E.J. Fundamentals of Marketing Tata McGraw Hill.
4. Mote. V. L. Paul. S and Gupta. G. S. Managerial Economics Concepts and Cases, Tata McGrw Hill Limeted.
5. Rustam & Daver. Salesmanship and Pubilicity.
6. Selected papers from scientific journals.

MBT 203- IMMUNO-TECHNOLOGY

Module I

Introduction

Immunology- fundamental concepts and anatomy of the immune system, Immune memory, Immune tolerance; Phagocytosis; Complement and Inflammatory responses; Haematopoiesis; Mucosal Immunity; Antigens - immunogens, haptens; Major Histocompatibility Complex - MHC genes, MHC and immune responsiveness and disease susceptibility, HLA typing.

Module II

Hybridoma Technology

Hybridoma techniques and monoclonal Ab production- myeloma cell lines, fusion of myeloma cell lines with Ab producing B cells , fusion methods, selection and screening methods, for positive hybrids, -cloning methods- production and purification and characterization of MAb. Application of MAb in biomedical research, in clinical diagnosis and treatment. Production of human MAb and their applications. Production of polyclonal Ab with different type of Ag: Ag preparation and modification, adjuvants, dose and route of Ag administration, collection of sera.

Module III

Immunotechniques-Antigen-Antibody interactions

Immunoprecipitation- mancini method, ouchterloney method, immune electrophoresis, rocket immunoelectrophoresis, crossed immunoelectrophoresis, agglutination and complement mediated immune reactions; Advanced immunological techniques - RIA, ELISA, Western blotting, ELISPOT and ELAST assay, peptide based immuno binding assay, peptide mapping, epitope mapping, fluorescence and photo illuminance based immunoassay, DELPHIA and SLFIA, concept of immunohisto / cyto-chemistry, immunofluorescence, flow cytometry and immunoelectron microscopy; detection of molecules in living cells, *in situ* localization by techniques such as FISH and GISH. Surface plasmon resonance, Biosensor assays for assessing ligand-receptor interaction, CMI techniques- lymphoproliferation assay, Mixed lymphocyte reaction, Cell Cytotoxicity assays, Apoptosis, Microarrays, Transgenic mice, Gene knock outs.

Module IV

New generation Vaccines: Immunobiotechnology

Vaccines and Vaccination, types of vaccines including new generation vaccines. Tumor immunology. Active and passive immunization; Live, killed, attenuated, sub unit vaccines; Vaccine technology- Role and properties of adjuvants, recombinant DNA and protein based vaccines, plant-based vaccines, reverse vaccinology; Peptide vaccines, conjugate vaccines; Antibody genes and antibody engineering- chimeric and hybrid monoclonal antibodies; Catalytic antibodies and generation of immunoglobulin gene libraries.

Module V

Clinical Immunology

T-cell cloning-importance of Ag presentation and MHC class II molecules in T-cell cloning, Ag specific and alloreactive T-cell cloning, use of T-cell cloning – cell cloning in understanding the immunologically relevant Ag and T-cell epitopes, application of T cell cloning in vaccine development. Hypersensitivity – Type I-V; Autoimmunity; Types of autoimmune diseases; Mechanism and role of CD4+ T cells; MHC and TCR in autoimmunity; Treatment of autoimmune diseases; Transplantation – Immunological basis of graft rejection; Clinical transplantation and immunosuppressive therapy; Tumor immunology – Tumor antigens; Immune response to tumors and tumor evasion of the immune system, Cancer immunotherapy; Immunodeficiency-Primary immunodeficiencies, Acquired or secondary immunodeficiencies.

Case studies.

Lab on Immunology:

1. Single Radial Immuno Diffusion.
2. Double diffusion.
3. Rocket Immuno electrophoresis.
4. Counter- Current Immuno electrophoresis.
5. Characterization of Immunoglobulins by SDS-PAGE.
6. Antibody titre by ELISA method.
7. Isolation of Lymphocytes from human blood and Culture
8. Culturing and maintenance of cell lines
9. Immunoblotting, Dot blot assays.
10. Abs Production.

Texts/References:

1. **Kuby, RA Goldsby, Thomas J. Kindt, Barbara, A. Osborne. Immunology, New Edition.**

2. Brostoff J, Seaddin JK, Male D, Roitt IM. Clinical Immunology, Gower Medical Publishing, New Edition.
3. Janeway et al., Immunobiology, Current Biology publications. New Edition.
4. Paul. Fundamental of Immunology, Lippencott Raven, New Edition.
5. Goding. Monoclonal antibodies, Academic Press. New Edition.
6. P. Delves, S. Martin, D. Burton and I. Roitt. Essential Immunology, Eleventh Edition (2006) Wiley-Blackwell Publishers, UK.
7. J. Kuby. Immunology, W H Freeman & Co Publishers. New Edition.
8. Hay F.C. and Westwood O.M.R. Practical immunology, Wiley-Blackwell Publishers, New Edition.
9. E. Benjamin, G. Sunshine, and S. Leskowitz. Immunology - A Short Course, Wiley-Liss Publishers, New York. New Edition.
10. D.P. Stites, J.D. Stobo and J.V. Wells. Basic and Clinical Immunology, Appleton & Lange Publishers. New Edition.
11. Selected papers from scientific journals.

MBT 204 -STEM CELL TECHNOLOGY

Module-I

Introduction to Stem Cells

Stem Cells: Definition, Classification and Sources, Blastocyst Culture, Xeno-free Derivation and Cryopreservation, Properties and Applications of Embryonic Stem Cells, Characterization of Human Embryonic Stem Cells, Stem Cells and their Developmental Potential. Culture, Subcloning, Spontaneous and Controlled Differentiation of Human Embryonic Stem Cells, *In Vivo* and *In Vitro* Differentiation of Human Embryonic Stem Cells, Feeder-free Culture of Human Embryonic Stem Cells,

Module-II

Standardization and Quality Assurance

Generation and Expansion of pluripotent Stem cells, Epigenesis in Pluripotent Cells, Organogenesis, Mammalian Nuclear Transfer Technology, Novel Strategies for the mobilization of HSC, GMP : clinical scale production of MSCs,

Module-III

Regenerative Medicine

Stem Cell therapy for Neurodegenerative Diseases: Parkinson's, Alzheimer, Spinal Cord injuries and other brain syndromes, Tissue system failures, Diabetic Cardiomyopathy, kidney failure, liver failure, Leukaemia, transplantation.

Module-IV

Cancer stem cells

Purification and characterization of cancer stem cells, therapeutic implications of cancer stem cells: Preventative and therapeutic strategies for cancer stem cells, Targeting acute myelogenous leukaemia stem cells, targeting cancer stem cell pathways: Hedgehog/GLI signalling, Notch signalling pathway, Wnt.

Module-V

Human Embryonic Stem Cells and society

Human Stem cells research: ethical considerations, stem cell religion consideration, Stem Cell based therapies: pre clinical regulatory consideration and patient advocacy, Intellectual property issues surrounding Human Embryonic Stem cells study.

Case studies.

Laboratory Exercise

1. Preparation of feeder cell culture.
2. Culturing of Stem cell line.
3. Isolation of cells from blastocyst.
4. Growing mesenchymal stem cell.
5. Preservation of cord blood.
6. Stem cell isolation from umbilical cord.
7. Types of cleavage, invertebrates, vertebrates, and permanent preparations – stains of stages of blastula
8. Development of Amphibian – Gastrulation – Metamorphosis
9. Sex determination – Drosophila (Prescribed assignments with problems in genetic)
10. Stem cells – Identification of cells by staining of bone marrow – (Animal example)

Texts/References:

1. S.F. Gillert, Sinauer. Developmental Biology, Associates inc., Massachusetts. New Edition.
2. Ethan Bier. The cold spring Cold Spring Harbor Lab Press, New York. New Edition.
3. Freshney, R. I. Culture of Animal Cells. Wiley-Liss. New Edition.
4. Masters, J. R. W. Animal Cell Culture – Practical Approach, Oxford Univ. Press. New Edition.
5. Basaga, R. Cell Growth and Division: A Practical Approach. IRL Press. New Edition.
6. Butler, M and Dawson, M. Cell Culture Lab Fax, Eds., Bios Scientific Publications Ltd., Oxford. New Edition.
7. Clynes, M. Animal Cell Culture Techniques. Springer. New Edition.

8. Mather, J.P and Barnes, D. Methods in Cell Biology, Animal Cell Culture Methods. Academic Press. New Edition.
9. Marshak. Cold spring Harbar Symposium Publication. New Edition.
10. Scott F. Gilbert. Development Biology, 6th edition.
11. Selected papers from scientific journals.

MBT 205 - PROTEOMICS & PROTEIN ENGINEERING

Module I

Architecture of Proteins: Amino acids, classification of proteins, Protein Structure: primary, secondary, tertiary and quaternary. Protein folding, thermodynamics and kinetics of protein folding, Protein Stability: protein stability & associated factors. Detection, identification and quantification of amino acids and proteins, *In-silico* protein modeling.

Module II

Control of Protein Function: Mechanisms of Regulation, Protein Interaction Domains, Regulation by Location, Effector Ligands: Competitive Binding and Cooperativity, Conformational Change and Allostery, Protein Switches Based on Nucleotide Hydrolysis, GTPase Switches: Small Signaling G Proteins, Signal Relay by Heterotrimeric GTPases, Protein Synthesis, Motor Protein Switches, Regulation by Degradation, Control of Protein Function by Phosphorylation, Regulation of Signaling Protein Kinases: Activation Mechanism, Cdk Activation, Two-Component Signaling Systems in Bacteria, Control by Proteolysis, Protein trafficking.

Module III

Protein – Protein Interactions:

Charting protein–protein interactions: Topoisomerase-based cloning, Univector plasmid-fusion system, Two-hybrid analysis protein-protein interactions in yeast, viral, bacteria systems. Use of phage display to detect protein-ligand interactions, Detecting interactions by protein fragment complementation assays.

Module IV

Protein Engineering & Protein Design:

Outline of bioengineering of macromolecules a multidisciplinary approach; Methods to alter primary structure of protein: site directed mutagenesis; examples of engineered proteins, protein design, principles and examples. Steps involved in protein engineering and protein modeling to the desired needs.

Module V

Techniques: Protein engineering

Physical methods of determining the three-dimensional structure of proteins (X-ray crystallography, Nuclear magnetic resonance spectroscopy, Cryoelectron microscopy, Neutron diffraction, Optical spectroscopic techniques, Vibrational spectroscopy, Raman spectroscopy),

Use of 2-D PAGE, sensitivity and resolution and representation of 2-D gels, multiplexed analysis to show expression profiles; circular dichroism (CD), MALDITOF and MALDITOFTOF, special strategies for qualitative and quantitative analysis. Protein array for expressional analysis, profiling and functional analysis, application of proteomics to medicine.

Case studies.

Lab on Protein Engineering

1. Using absorbance coefficients and extinction coefficients to estimate protein concentration
2. Protein quantitation when contaminating nucleic acids are present
3. Measuring protein concentration by colorimetric assay - the Bradford assay
4. The nitric acid method for protein estimation in biological samples
5. Quantitation of Tryptophan in Proteins
6. The CAT (chloramphenicol acetyltransferase) Assay
7. Use of Luciferase in a reporter assay
8. *In vitro* translation - Determining amino acid incorporation
9. Casting Immobilized pH Gradients (IPGs)
10. Carboxymethylation of cysteine using iodoacetamide/iodoacetic acid
11. Analyzing Protein Phosphorylation

Texts/References:

1. **TE Creighton. Protein Function A Practical Approach, 2005. W.H. Freeman & Company. New Edition.**
2. **Thomas E Creighton , Creighton. Proteins: Structures and Molecular Properties, W.H. Freeman & Company. New Edition.**
3. **N J Darby, T E Creighton. Protein Structure (In Focus), W.H. Freeman & Company. New Edition.**
4. **Charles J Dutton, Mark A Haxell, Hamish A. I. McArthur and Richard G. Wax Marcel Dekker. Peptide Antibiotics - Discovery, Modes of Action, and Applications, New Edition.**
5. **Peter Goodenough. Protein Engineering II CPL Press. New Edition.**
6. **Lilia Alberghina. Protein Engineering for Industrial Biotechnology, CRC Press. New Edition.**
7. **Loïc Faye and Véronique Gomord. Recombinant Proteins From Plants - Methods and Protocols, Humana Press. January 2009.**

8. Sheldon J Park, Jennifer R Cochran. Protein Engineering And Design, CRC Press. New Edition.
9. Paul R Carey. Protein Engineering And Design, Academic Press. New Edition.
10. Paul Wrede, Gisbert Schneider, Walter De Gruyter. Concepts in Protein Engineering and Design: An Introduction, New Edition.
11. Nediljko Budisa, Wiley-VCH Verlag GmbH. Engineering The Genetic Code: Expanding The Amino Acid Repertoire For The Design Of Novel Proteins. New Edition.
12. Selected papers from scientific journals.