(ii) Questions :9 Sub. Code: 3 4 8 8 Exam. Code: 0 4 3 8

M.Sc. Bio-Technology 4th Semester (2054)

INTELLECTUAL PROPERTY RIGHTS, BIOSAFETY AND BIOETHICS

Paper: MBIO-403

Time Allowed: Three Hours]

[Maximum Marks: 80

Note: Attempt five questions in all by selecting one question from each unit. Question No. 1 is compulsory. All questions carry equal marks.

(Compulsory)

- 1. (a) Which IPRs in India cover:
 - (i) Mere new design of a Thermal Cycler and
 - (ii) New plant variety?
 - (b) What are derivative works?
 - (c) What is non-obviousness?
 - (d) What are Boolean Operators?
 - (e) What were Exclusive Marketing rights?

- (f) Give the main features of Geographical Indications.
- (g) What is Unfair Means competition?
- (h) When is any organism designated as bioweapon? 2×8

UNIT-I

- (a) A researcher develops a new method of production of a modified enzyme in a genetically engineered microbe for degrading plastics. He also created a new substrate for growing the microbe. He commercialized the enzyme and named it "Polyendenzyme" and packaged it in new design pack. He created an instruction manual for use of the enzyme. Enlist the IPRs under which all of his inventions can be protected with justification for each.
 - (b) Are computer software and architectural designs patentable? Justify your answer with reasons.

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 - (c) Discuss the criteria for an invention to be eligible as patentable subject matter under Article 27 of TRIPs agreement. 6
- 3. (a) Why was GATT created and what were its functions? Why did WTO come into existence?
 - (b) Mention in brief the structure of Patent specification writing while filing Indian Patent.

(c) What is prior art search and why is it carried out? Mention the various methods of prior art search.

UNIT—II

- 4. (a) What is patent infringement and what are the various types of infringement? What does infringement lead to? Mention the procedural aspects of patent litigation.
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 - (b) Discuss the events which led to patenting of life forms. What was the economic impact of patenting life forms?
- (a) What is an IDA? Discuss the function, role and responsibilities of IDA.
 - (b) Compare the protection of plants by PPA, PVPA and Utility patents.
 - (c) Schematically present the stepwise filing procedure of patents under PCT.

UNIT-III

- 6. (a) Discuss two case studies which show the public acceptance issues of Biotechnology and Biotechnology products. 8
 - (b) Discuss with the help of SWOT analysis the status of biotechnology research and industries in India.

- 7. (a) Mention the status of biotechnology patenting in developed and developing countries.
 - (b) Define Bioethics and mention the principles of bioethics. Discuss the bioethics related to stem cells and cloning.

UNIT—IV

- 8. (a) Explain the GLPs required for safety in biotechnology laboratories.
 - (b) Discuss the principles and objectives of MOEF, DBT and GEAC.
- 9. (a) What is AIA and BCH in Cartagena protocol and discuss their roles?
 - (b) Discuss the role and importance of the following International regulatory authorities:
 - (i) USDA
 - (ii) APHIS.

 $4 \times 2 = 8$