### 1058

# M.Sc. (Biotechnology) Fourth Semester MBIO-403: Intellectual Property Rights, Bio-safety and Bioethics

## Time allowed: 3 Hours

#### Max. Marks: 80

**NOTE:** Attempt five questions in all, including Question No. I which is compulsory and selecting one question from each Unit.

x-x-x

I. Attempt the following:-

- a) What is disclosure requirement?
- b) Define Biosafety?
- c) What are Exclusive Marketing rights?
- d) What are patent of addition and patent of division?
- e) Under which treaty does IDAs fall and when did it come into force?
- f) Define Bioethics?
- g) Give the features of Geographical indications?
- h) What is PPA and for which organisms is it applicable?

(8x2)

### UNIT-I

- II. a) A researcher developed a new enzyme producing microbe by r-DNA technology which can degrade lignin, the waste in the paper industry. He also develops a new method to isolate\_and purify the enzyme and designs the package and an emblem with the name 'Laczyme" to commercialize the product. Which intellectual property rights will cover his various inventions and state why?
  - b) Discuss in detail the main features of TRIPs agreement? When did India become the member country of TRIPS? (2x8)
- III. a) What are the basic requirements of patentability? Discuss in detail the stepwise procedure of filing an Indian patent?
  - b) Discuss main features and the mode of protection of the following IPRs in brief:
    - a) Copyrights
    - b) Trademarks

#### UNIT – II

- IV. a) Give an account of patenting of microorganisms and its impact in the biotechnology industry?
  - b) Mention the substantive aspects of litigation and explain the procedure of litigation with examples in Biotechnology? (2x8)

(2x8)

- V. a) Discuss the various amendments made in the Indian Patent Laws in 1995 and implemented in 2005? Why were these amendments necessary?
  - b) Discuss why IDAs are established? Mention the various features of IDA and requirements of a depository to become and maintain as IDA? (2x8)

## <u>UNIT – III</u>

- VI. a) With the help of case studies explain the issues related to public acceptance of Biotechnology?
  - b) Give an account of social and ethical implications of various aspects of Biotechnology? (2x8)
- VII. a) With the help of SWOT analysis give a detailed account of challenges faced by Indian Biotechnology research and Industries?
  - b) Describe Biological weapons and their unethical use can harm the society? (2x8)

### $\underline{UNIT} - IV$

- VIII. a) Mention the various kinds of laboratory contaminants and how can they be tackled using Good Lab Practices?
  - b) What is Biosafety management and how can we use it for environmentally safe use of biotechnology? (2x8)
  - IX. a) Why was Cartegana protocol established and when and where is it applicable?
    - b) Discuss the role of the following Regulatory bodies:
      i) USDA
      ii) EPA (2x8)

(2x8)

*x*-*x*-*x*