

1059

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. 1 which is compulsory and selecting one question from each Unit.

x-x-x

I. Attempt the following:-

- a) What are tangible and intangible properties?
- b) What is patent of Addition and patent of division?
- c) Which IPRs in India covers:-
 - i) mere new design of a cosmetic cream bottle
 - ii) Architectural designs?
- d) Give the two conditions for protection of a Trademark?
- e) What are the major functions of FDA?
- f) Define Bioethics?
- g) What are related rights?
- h) Mention any four good Lab practices in Biotechnology labs? (8x2)

UNIT - I

- II. a) Discuss the basic requirements of patentability? Give the process of filing a patent under PCT? What are patent claims?
- b) Dr. Aseem discovers a microbe having an enzyme laccase which can degrade lignin. He then uses r-DNA technology to improvise this enzyme to enhance its efficiency and scales up the production using a newly designed fermenter. He also develops a manual for operating the new fermenter. He names his modified enzyme as "Laczyme" to commercialize it. List the inventions and creations which he can protect under various IRs and Which IPRs he can use to protect all his products, why? Explain the main features of these IPRs? (8,8)
- III. a) What do you understand by patentable subject matter? What is prior art search and how is it carried out?
- b) Discuss the major amendments made in the Indian Patent act 2005, under the Trips agreement? (8,8)

P.T.O.

(2)

UNIT – II

- IV. a) What are disclosure requirements for biotechnology patents? Discuss the landmark judgment which brought a major change in the biotechnology patents especially the microorganisms and the development post this judgment in the field of biotechnology patents?
- b) What is patent infringement and the types of infringements? What are the procedural aspects of patent litigation and its significance? (8,8)
- V. a) How is new plant varieties protected in India? How is it different from PPA, PVPA and Utility Patents?
- b) What is an IDA and discuss its role? Give the depository considerations under IDA? (8,8)

UNIT – III

- VI. a) On the basis of any two case studies/experiences discuss the issues of public acceptance for biotechnology and biotechnology products?
- b) On the basis of SWOT analysis, explain the major challenges faced by Indian biotechnology industries? (8,8)
- VII. a) Discuss how biotechnology plays a role in tackling hunger especially in developing and under developed countries?
- b. Mention the social and ethical implications of biotechnology and its various products? (8,8)

UNIT – IV

- VIII. a) Discuss the main objectives of Cartagena Protocol? What is BCH and what is its purpose?
- b) How are good safety practices and GLP maintained in a Biotechnology Lab? (8,8)
- IX. a) Discuss the how is Biosafety management carried out and its importance?
- b) Discuss the function and importance of the following regulatory bodies in maintaining the safety of Biotechnology products:
- i) USDA
- ii) EPA (8,8)

x-x-x