**R07** 

## IV B.Tech I Semester Examinations,November 2010 BIO ETHICS, BIO SAFETY AND INTELLECTUAL PROPERTY RIGHTS

### **Bio-Technology**

Time: 3 hours

Code No: 07A72303

Max Marks: 80

## Answer any FIVE Questions All Questions carry equal marks

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1. Salient features of TRIPS [16]2. Explain the following (a) Use of animals in Biomedical Science (b) Are there alternatives to research involving animals? (c) Are findings from research on animals relevant to humans? [8+4+4]3. Write short notes on the following (a) Moral rights (b) Originality conundrum [8+8]4. (a) What are the defenses in the patent law applicable to biotechnology patents. (b) In the case of infringement of a patented process on whom does the burden of proof lie under the TRIPS agreement? [8+8]5. Explain the following: (a) How to create markets for Biodiversity (b) Policies for Biodiversity. [8+8]6. Write short notes on the following (a) TRIPS and copyright (b) TRIPS and GI [8+8]7. Discuss the public perception in the success and failure of rDNA products. [16]8. Write a short note on the following (a) Applicability of GCP (b) GCP has nothing to do with efficacy-explain [8+8]

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[6+5+5]

[16]

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- 1. What is meant by the following terms as used in the protection of plant varieties and farmer's rights act 2001
  - (a) Farmer
  - (b) Variety
  - (c) Essentially derived variety
- 2. Mission and activities of WIPO

3. Give an account on the history of FDA regulations. [16]

- 4. Explain the following
  - (a) The process of patent application from the date of filing to the grant
  - (b) Sealing of the patent [8+8]
- 5. Explain the significant role that a precautionary approach plays in promoting Biosafety. [16]
- 6. Explain the following
  - (a) Engineering the pro-vitamin biosynthetic pathway into rice endosperm.
  - (b) Edible vaccines.

[8+8]

- 7. (a) Discuss the limitations on the rights permitted by Rome convention.
  - (b) What are the main contributions of the phonogram convention? [8+8]
- 8. Identify
  - (a) What factors and principles are most important in deciding whether it would be right for a particular nation to invest in a programme of nuclear power?
  - (b) How these factors or principles should be ranked as to importance.
  - (c) What conclusion the operations of those factors suggest. 8+4+4]

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- 1. Write short notes on
  - (a) FAO
  - (b) WIPO
- 2. Write a short note on the following
  - (a) History of GCP and GMP
  - (b) Identify regulations that institutions are faced with in the drug development process. [8+8]
- 3. Explain the guidelines for labeling of genetically modified foods. [16]
- 4. Explain the WTO Agreement on trade related aspects of IPR. [16]
- 5. Explain the following
  - (a) Why do we need an international Biosafety Agreement?
  - (b) What is the precautionary approach? How is it reflected in the protocol?

[8+8]

- 6. Write short notes on the following
  - (a) Benefits of Patent law treaty for the patent applicant.
  - (b) In which situations compulsory license of a patent granted [8+8]
- 7. Explain the following
  - (a) Animal Transgenesis
  - (b) Are there limits to animal Transgenesis?
  - (c) Do animal feel pain
  - (d) Reason and Morality [4+4+4+4]
- 8. Copyright in a literary work confers a bundle of rights on the author. What rights make up this bundle? [16]

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1. Explain the following (a) What animals are used in research? (b) Areas of research and testing in which laboratory animals are used (c) Are there alternatives to research involving animals? [8+4+4]2. Explain the best practices and strategies for staying compliance with Good Clinical Practices and Good Manufacturing Practices [16]3. Write short notes on benefits of protecting (a) TKDL (b) TCE's [8+8]4. Write short notes on (a) The key principles underlying the operation of WTO. (b) To what extent WTO principles make economic sense. [8+8]5. Write short notes on the following (a) Indication of source (b) Appellation of origin [8+8]6. Write short notes on the following (a) TRIPS agreement and trademarks (b) TRIPS agreement and trade secrets [8+8]7. Explain the significance of transgenic crops in the third world. [16]

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8. Explain the Biosafety and trade issues for developing countries.