

**GUJARAT NATIONAL LAW UNIVERSITY
GANDHINAGAR**

Course: Law of Biotechnology and Challenges of Traditional Knowledge
Semester- II (Batch: 2020-21)

End Semester Online Examination: June 2021 (LLM)

Date: 28th June, 2021

Duration: 8 hours

Max. Marks: 50

Instructions:

- The respective marks for each question are indicated in-line.
- Indicate correct question numbers in front of the answer.
- No questions or clarification can be sought during the exam period, answer as it is, giving reason, if any.
- Word Limit: minimum 750 words

Part A**Marks**

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|-----|---|------|
| Q.1 | What are clinical trials? Why are they important? Add a note on salient features of New Drug and Clinical Trial Rules, 2019. | (10) |
| Q.2 | Zolgensma - gene therapy drug which has a reported list price of £1.79 million(Rs. 18 crore) per dose is labelled as the most expensive drug in the world . What are the ethical and legal implications of such drugs? Add a note on challenges of gene therapy. | (10) |

Part B**(Answer Any Three)**

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| Q.3 | “Whether a thing is alive or not is irrelevant to patent law. Significant is alone whether it is a product of nature or of human invention”. US Supreme Court in <i>Diamond v. Chakrabarty</i> , 447 U.S. 303 (1980). | (10) |
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“The rule against patents on naturally occurring things is not without limits, for all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas, and too broad an interpretation of this exclusionary principle could eviscerate patent law. Patent protection strikes a delicate balance between creating incentives that lead to creation, invention, and discovery and impeding the flow of information that might permit, indeed spur, invention.” US Supreme court in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* - 569 U.S. 576, 133 S. Ct. 2107 (2013)

Keeping these two decisions in reference, analyze the evolution and development of patent regime in the US in the context of biotechnology invention and examine the similarity of the same with the patent system of India and its interaction with biotechnology.

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| Q.4 | Discuss the problem of Bio-piracy and analyse the international regime governing bio-prospecting, access and benefit sharing. Deliberate on the steps taken by India in protecting its traditional knowledge and give suggestions for further reforms. | (10) |
| Q.5 | Genetically modified organisms/food are a one stop solution for food security but at the same time they pose serious threat to our environment. Discuss the pros and cons of | (10) |

genetically modified organisms and its application. Review its regulatory mechanism in India.

- Q.6 Share your views on cloning. Critically analyze the existing international framework regulating cloning. (10)
