

NATIONAL LAW UNIVERSITY AND JUDICIAL ACADEMY, ASSAM

PROGRAMME: B.A., LL.B (HONS.) FYIC

DETAILS OF COURSE OFFERED

ODD SEMESTER (IX) - ACADEMIC YEAR :.....

| SL. | COURSE | COURSE | | | | |
|-----|----------|--------------------|-------------|-------------|----|----|
| NO | CODE | TITLE | L | T/P | CR | СН |
| 1 | 904 | IPR IN | 4 | 1 | 4 | |
| | IPR SP V | PHARMA INDUSTRY | PER WEEK | PER WEEK | | |

- A. CODE AND TITLE OF THE COURSE: 904 IPR SP V, IPR IN PHARMA INDUSTRY.
- B. COURSE CREDIT: 4 (TOTAL MARK (200)
- C. MEDIUM OF INSTRUCTION: ENGLISH
- D. COURSE COMPILED BY: PARTHA PRATIM MEDHI
- E. COURSE INSTRUCTOR: PARTHA PRATIM MEDHI

1. COURSE OBJECTIVES

The pharma industry has registered unprecedented growth in the past decades fuelled by high burden of disease, higher disposable income, healthcare infrastructure, etc. The pharma industry will continue to grow organically and inorganically through alliances, joint ventures, and mergers and acquisitions. The focus is on improving efficiency and productivity through novel ideas and business models. The major growth drivers for the pharma industry include developments in healthcare insurance, medical technology, and healthcare financing, and improving healthcare access . These innovations lead to discovery of new life-saving drugs and have to be protected through intellectual property rights (IPRs). Patents provide pharma companies exclusive rights to market drugs and prevent others to manufacture, sell, and make these drugs for a period of 20 years. IPR is a prerequisite for pharma companies for identification, planning, commercialization, and protection of invention. It is also an important tool to protect investment, time, and effort and encourages healthy competition—thus promoting industrial development and economic growth. IPRs also provide incentives to pharma companies to invest in research and development. This paper seeks to provide insight into the expanding scope of IPR laws and Pharma Industry, along with the inevitable challenges it brings from a worldwide lens on the matter

2. TEACHING METHODOLOGY

Collegial presentation

Interactive pedagogical techniques

Case study method

Articles based discussions

Debate oriented and negotiation rounds on critical environmental issues

Legislative and case analysis of Landmark and latest legal instruments and case

laws respectively

Documentary screening and open house discussions

Surprise tests on fortnight /weekly basis

3. Course outcomes

- The students after the completion of this course are expected to have fundamental knowledge on IPR in Pharma Industry
- They shall be capable of knowing the core issues of IPR in Pharma Industry
- They will be equipped with interest to take up Intellectual Property Law a subject at honours levels, Masters Level and PhD level.

4. Course Evaluation Method

The course shall be assessed for 200 marks. The Evaluation scheme would be as follows:

Internal assessment: 70% (140 marks) External assessment: 30% (60 marks)

| Sl. No. | Internal Assessment | |
|------------|----------------------------------|-------------------------|
| 1 | 2 Assignments | 2 x 20 marks = 40 marks |
| 2 | Seminar/Group Discussion | 20 marks |
| 3 | Class Test (Twice in a Semester) | 2 x 35 marks = 70 marks |
| 4 | Attendance in Class | 10 marks |
| 5 | Semester End Examination | 60 marks |

5. DETAILED STRUCTURE OF THE COURSE (SPECIFYING COURSE

MODULE I

History of Pharmaceutical Industry, Law and Pharmaceutical Industry, Protection of medical Inventions, Protection of Consumers and Families, IPRs involved in Pharma Industry: Patents, Industrial designs, Trademarks, Copyright, Trade Secrets,

MODULE II

Patent and Pharma Industry, Patents relating to pharmaceutical inventions, Patents relating to formulations and compositions, Criteria of Patentability, Impact of WTO on Pharmaceutical Patents

MODULE III

Trademark and Pharma Industry, Pharma Trademark infringement and passing off, The concept of colour as a Mark in Pharma Industry, Phonetic Similarity and Pharma Industry, Challenges of Trademark Management in Pharma Industry.

MODULE IV

Copyright and Pharma Industry, Copyright License for Pharmaceutical Industry, Industrial Design and Pharma Industry, Digital design for pharmaceutical product and process development, Trade secrets in Pharma Industry

6. PRESCRIBED READINGS

Books:

- (a) Law of Patents With A Special Focus On Pharmaceuticals In India Feroz Ali Khader (2011), Lexis Nexis
- (b) Intellectual Property Rights in Pharmaceutical Industry: Theory and Practice- BayyaSubba Rao and P. V. Appaji (2019), BSP Books.

Journal Articles:

- G.G. Nair, Impact of TRIPS on Indian Pharmaceutical Industry, Journal of Intellectual Property Rights, Vol.13, Sept. 2008, pp 432-441.
- 2. Damodaran A.D., Indian Patent Law In The Post TRIPS Decade: S&T Policy Appraisal, NISCAIR (Sept. 2008),
- 3. Chaudhuri, Sudip (2005). The WTO and India's Pharmaceuticals Industry: Patent Protection TRIPS and Developing Countries. Oxford University Press, New Delhi.
- 4. Griliches, Z. (1990). "Patent statistics as economic indicators: a survey", Journal of Economic Literature, Vol. 28 (4), 1661–1707.
- 5. Dey, S. The new national IPR Policy 2016: implications for the pharmaceutical industry. *Gggi Management Review*.
- 6. Mitsumori, Yaeko. *The Indian Pharmaceutical Industry: Impact of Changes in the IPR Regime*. Springer, 2018.