Ipr, biosafety and regulatory framework for pharma industries

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Abstract
IPR, Biosafety and Bioethics covers a broad coverage of three areas of patenting--intellectual property rights (IPR), biosafety and bioethics. Intellectual Property Rights are the rights given to persons over the creations of their minds. Types of Intellectual property rights (IPR) such as copyright, patent, trademarks, industrial designs, trade secrets, geographical indications and so on are meant to protect creators of new inventions, their families and consumers. Strong IP rights help consumers make an educated choice about the safety, reliability, and effectiveness of their purchases. Enforced IP rights ensure that products are authentic, and of the high-quality that consumers recognize and accept. Biosafety is meant to create an appropriate bio safe working environment to protect workers from laboratory-induced infections who work with deadly disease-causing microorganisms such as the present pandemic Covid-19 virus, for their characterization, diagnostics or therapeutics and vaccine development purposes which are posing increasingly potential biosafety problems for healthcare personnel and laboratory workers. Bioethics is the typically controversial ethical issues emerging from new situations and possibilities brought about by advances in biology and medicine. Regulatory Framework: India is home to about 10,500 manufacturing units and over 3,000 pharma companies. India exports all forms of pharmaceuticals from APIs to formulations, both in modern medicine and traditional Indian medicines. The growth of pharmaceutical market depends upon various factors including regulatory legislations and drug regulatory system. Two major government agencies responsible for drug regulation and control are: 1) the Drugs Controller of India (DCI), and 2) the State Food and Drug Administrations (FDAs). The DCI, under the Ministry of Health, has five main functions: 1) Controlling the quality of imported drugs, 2) Coordinating the activities of State FDAs, 3) Enforcing new drug legislation, 4) Granting approval to new drugs, and 5) Controlling the quality of imported drugs. The present paper highlights IPR and some of the risks & regulations of biosafety for pharma industries

Biography:
Dr. Philomena George has completed her PhD 36 years ago from Mysore University and postdoctoral studies from Stanford University School of Medicine. She was the Dean, Director and Professor & HOD of Biotechnology of Karunya University, Coimbatore, Bharath University Chennai, and Senior Scientist and Technology Development Manager in many Biotechnology Industries. She has won many National and International Awards including Best Faculty Award, Best Researcher Award, and Lifetime Achievement Awards. She has published 4 books and more than 100 papers in reputed journals and has been serving as an editorial board member in many International Journals

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