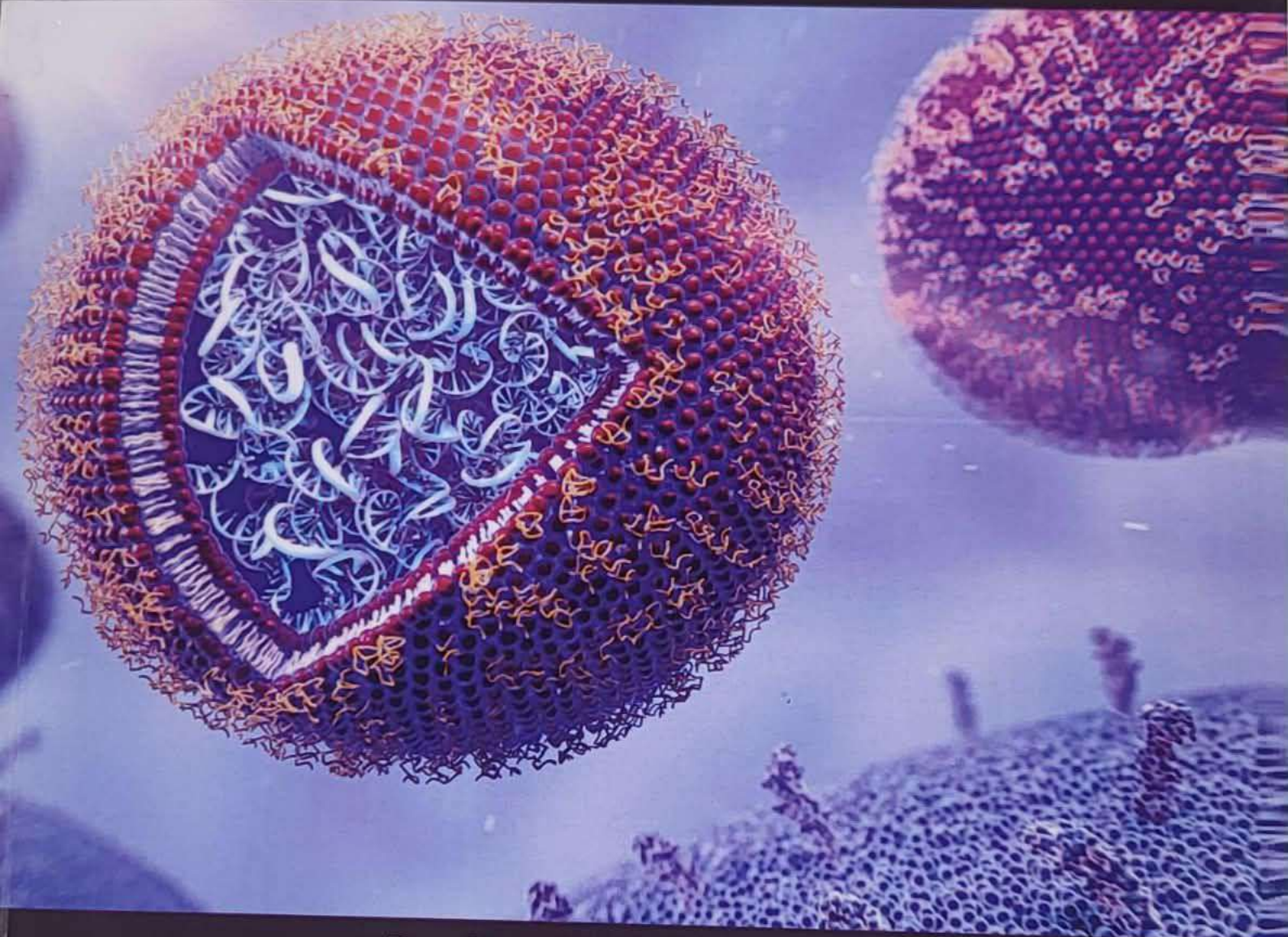


APPLICATIONS AND EMERGING TRENDS IN PHARMACEUTICAL NANOTECHNOLOGY



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LIST OF CONTRIBUTORS

S. No.	Chapter Title	Author(s)
1	Application of Nanotechnology in Cancer Therapy: Targeted Drug Delivery and Tumor Treatment	Dr. Ramesh Gupta, Ms. Chandani Nigam*, Mr. Ashirvad Jaiswal
2	Intellectual Property Rights and Patent Strategies in Nanotechnology-Based Pharmaceuticals	Abdul Baseer Khan, Reetu*, Ashutosh Kumar Yadav
3	Nanotechnology-Based Drug Delivery Systems for Infectious Diseases	Sakshi Srivastava*, Dr. Ramesh K. Gupta
4	Good Manufacturing Practices (GMP) and Regulatory Guidelines for Nanomedicines	Subhajit Roy
5	Artificial Intelligence and Machine Learning in Drug Delivery System Design: Applications and Future Perspectives	Jyoti Yadav*, Prakash Singh Patel, Ravi Kumar
6	Patent Strategies and Intellectual Property Management in Nanotechnology-Based Drug Delivery	Himanshu Singh*, Dr. Abdul Baseer Khan, Harshit Verma, Vandana Tiwari, Dr. Sushma Chaudhary
7	Pharmaceutical Nanotechnology: Principles, Drug Delivery, and Emerging Trends	Sadhana Singh*, Pushp Raj Singh, Vishal Kumar Agrahari
8	Liposomes in Targeted Drug Delivery: Preparation, Characterization, and Applications	Shahrukh Khan*, Zahid Husain

2 INTELLECTUAL PROPERTY RIGHTS AND PATENT STRATEGIES IN NANOTECHNOLOGY- BASED PHARMACEUTICS

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2.1 ABSTRACT

The convergence of nanotechnology and pharmaceutical sciences has established nanotechnology-based drug delivery systems as a transformative therapeutic paradigm, while simultaneously generating unprecedented challenges for intellectual property (IP) frameworks. This chapter examines intellectual property rights (IPR) and patent strategies in nanopharmaceutics, encompassing foundational patentability criteria, nanomedicine-specific IP challenges, lifecycle management strategies, and a comparative regulatory analysis across the United States, European Union, and India. Recent advances between 2022 and 2025 in CRISPR-based nanomedicine patents, Artificial Intelligence (AI)-AI-assisted drug delivery design, personalized mRNA cancer vaccines, and next-generation lipid nanoparticle (LNP) technologies are critically evaluated. The role of AI patent tools, including PatSnap, Derwent Innovation, and Lens.org, is assessed with respect to its capabilities, limitations, and ethical concerns. Case studies encompassing Doxil, Abraxane, ONPATTRO, and mRNA-4157/V940 illustrate applied IP strategy. Ethical dimensions, including equitable access, evergreening, and technology transfer obligations, are also discussed.

KEYWORDS: AI Patent Drafting, CRISPR Nanomedicine, Evergreening, Intellectual Property Rights, Lipid Nanoparticles, Mrna Therapeutics, Nanotechnology Patents, Nanopharmaceutics, Personalised Nanomedicine

2.2 INTRODUCTION

Nanotechnology-based drug delivery systems operating within the 1–1000 nm range exhibit physicochemical properties categorically distinct from bulk-phase materials, generating profound implications for intellectual property protection. The reformulation of paclitaxel as albumin-bound nanoparticles, as seen with Abraxane, illustrates this principle: an unchanged active pharmaceutical ingredient produces qualitatively distinct pharmacokinetics, reduced toxicity, and altered tumor accumulation. This raises fundamental questions regarding whether such reformulations constitute patentable pharmaceutical compositions, novel processes or new medical uses. The global nanomedicine market, valued at approximately USD 211 billion in 2023 and projected to exceed USD 500 billion by 2030, has intensified the strategic acquisition and defense of IP protection across the pharmaceutical industry. The period from 2022 to 2025 has been particularly transformative, characterized by the clinical translation of CRISPR-based nanomedicine, AI-assisted delivery system design, unprecedented proliferation of mRNA-LNP patent filings, and the first Phase III evaluations of personalized nanoparticle cancer vaccines. This chapter guides the reader from foundational IP principles through current complexities while maintaining a consistent focus on both practical and ethical dimensions.