# Advanced Patent Law and Strategy in Biotechnology Training Course

Professional Development Training Course Outline

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| **Category** | Biotechnology and Pharmaceutical Development | **Duration** | 10 Days |
| **Base Fee** | $4,000 USD | **Delivery Mode** | Online / On-site Hybrid |

## Course Introduction

The biotechnology sector is experiencing unprecedented growth, driven by breakthroughs in CRISPR-Cas9 gene editing, advanced biologics, and AI-driven drug discovery. This rapid innovation, however, is met with an increasingly complex and high-stakes intellectual property (IP) landscape. Protecting multi-billion-dollar R&D investments and securing a competitive advantage requires patent professionals and strategic leaders to move beyond foundational knowledge. The failure to navigate global patent harmonization, freedom-to-operate (FTO) risks, and the ethical implications of emerging technologies can result in catastrophic financial and legal exposure. Advanced Patent Law and Strategy in Biotechnology Training Course provides the advanced strategy and litigation preparedness necessary to master the nuances of the biotech IP lifecycle, transforming a patent portfolio from a legal requirement into a pivotal strategic business asset.

This training is a deep dive into the commercialization and enforcement of next-generation biotech IP. We focus on cutting-edge issues like the patentability of AI-generated inventions, the regulatory-IP interface for biosimilars, and developing robust global filing strategies via the Patent Cooperation Treaty (PCT). Participants will master IP due diligence for M&A, perform sophisticated infringement risk analysis, and learn to leverage trade secret protection for proprietary bioprocesses. The curriculum is grounded in real-world case studies from the seminal CRISPR patent battle to recent biologics litigation ensuring that attendees acquire immediately actionable skills to construct and defend a formidable, high-value biotech patent portfolio in a dynamic, global bio economy.

## Programme Curriculum

**Advanced Patent Law and Strategy in Biotechnology Training Course**

**Introduction**

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**Course Duration**

10 days

**Course Objectives**

1. Master the patentability criteria for complex biologics and advanced diagnostics across key global jurisdictions
2. Develop a robust IP portfolio strategy for therapeutics, personalized medicine, and AI-driven drug discovery aligned with long-term business goals.
3. Execute sophisticated Freedom-to-Operate (FTO) analyses to mitigate infringement risk in R&D pipelines and product launches.
4. Navigate the legal and ethical implications of CRISPR-Cas9 and gene-editing technologies patent ownership disputes.
5. Formulate a global patent prosecution strategy utilizing the PCT and regional phase nationalizations for optimal worldwide protection.
6. Understand and strategically leverage the interface between patent protection and regulatory data exclusivity
7. Conduct comprehensive IP due diligence for mergers & acquisitions (M&A) and strategic licensing agreements in the biotech sector.
8. Draft patent claims with advanced specificity to withstand legal challenge, focusing on method claims, product-by-process, and antibody patents.
9. Implement best-practice systems for protecting crucial bioprocess trade secrets and confidential data against internal and external threats.
10. Analyze the emerging legal landscape for AI-generated inventions and the challenges of inventor/ownership attribution in machine learning models.
11. Prepare for and effectively manage biotech patent litigation, including strategies for injunctions, damages calculation, and alternative dispute resolution (ADR).

12. Design effective technology transfer and commercialization frameworks for academic and corporate research assets.
13. Calculate and maximize the commercial valuation of a biotech IP portfolio for fundraising and investor communications.

**Target Audience**

1. In-House Patent Counsel and IP Attorneys.
2. Senior R&D Scientists and Chief Scientific Officers (CSOs).
3. Business Development and Licensing Professionals.
4. Patent Agents.
5. Venture Capital (VC) and Private Equity.
6. Technology Transfer Officers.
7. Regulatory Affairs Specialists.
8. Senior Executives (CEOs, CFOs)

**Course Modules**

**Module 1: Foundational IP Strategy in the Bioeconomy**

- Review of core Patentability Criteria specific to biological matter.
- The fundamental legal distinction between Biologics and traditional Small Molecule Drugs.
- Strategic use of Trade Secrets and Patents for proprietary cell lines and manufacturing processes
- Understanding the legal implications of the Enablement and Written Description requirements in the US and Europe.
- Case Study: Analyzing the US Supreme Court's ruling on the enablement of broad antibody claims.

**Module 2: Advanced Biologics and Antibody Patenting**

- Claim Drafting for complex molecular entities.
- Strategies for patenting Monoclonal Antibodies, including epitope and therapeutic use claims.
- Overcoming Prior Art challenges posed by large public sequence databases and published literature.
- The strategic timing of PCT filing and the use of continuation/divisional applications in major jurisdictions.
- Case Study: Analyzing the prosecution history and enforcement of foundational patents for a top-selling TNF-alpha inhibitor

**Module 3: CRISPR, Gene Editing, and Nucleic Acid IP**

- Navigating the CRISPR-Cas9 patent landscape.
- Patentable subject matter issues for Gene Therapy and Cell Therapy
- Ethical and legal challenges in patenting Human Genes and Genomic Data following key Supreme Court precedents
- Developing design-around strategies and assessing infringement risk in a rapidly evolving gene-editing landscape.
- Case Study: CRISPR Patent Battle. Deep dive into the interference proceedings and their global licensing implications.

**Module 4: Regulatory Exclusivity and the IP/FDA Interface**

- The interplay between Hatch-Waxman Act and the BPCIA
- Understanding and exploiting Data Exclusivity, Orphan Drug Status, and Pediatric Exclusivity.
- Strategic considerations for originator companies and biosimilar applicants.

- Developing a strategic approach to Patent Term Extension (PTE) and Supplementary Protection Certificates (SPCs) in the EU.
- Case Study: Analyzing the BPCIA litigation surrounding a major biosimilar entry, focusing on the procedural Patent Dance details.

**Module 5: Freedom-to-Operate (FTO) and Clearance**

- Methodology for conducting an in-depth FTO search and analysis for new product candidates and platform technologies.
- Structuring a robust "Non-Infringement" and "Invalidity" legal opinion to mitigate willful infringement risk.
- Strategies for proactively designing around competitor patents to avoid litigation entirely.
- Managing patent thickets in crowded therapeutic areas and identifying white space.
- Case Study: Examining the legal and financial fallout from an FTO failure and subsequent damages.

**Module 6: Patent Drafting for Litigation Preparedness**

- Techniques for drafting claims that anticipate and survive Inter Partes Review and European Opposition Proceedings.
- The critical role of the Specification in supporting claim breadth and overcoming validity challenges.
- Drafting effective dependent claims and defining the proper scope of the Prior Art section.
- Strategies for maximizing Claim Construction in litigation through clear and consistent use of definitional language.
- Case Study: Analyzing a successfully defended patent against an IPR challenge, focusing on the original claim language and supporting disclosure.

**Module 7: Global Patent Strategy and the PCT System**

- Mastering the Patent Cooperation Treaty framework for efficient and cost-effective multi-jurisdictional filing.
- Strategic decision-making for national phase entry in key markets and emerging markets.
- Understanding the different standards for inventorship and patentable subject matter across major global offices.
- Leveraging the European Patent Convention (EPC) Opposition procedure for strategic competitive advantage.
- Case Study: Developing a global filing strategy timeline for a novel gene therapy vector from provisional filing to grant in 10 jurisdictions.

**Module 8: AI-Driven Innovation and IP Ownership**

- Addressing the challenge of AI-Generated Inventions and the current status of AI as an Inventor
- Patentability of Machine Learning Algorithms and Biotech Software
- Protecting the Training Data and Model Weights as high-value Trade Secrets.
- IP implications of open-source AI models and collaborative research platforms.
- Case Study: Exploring the patent filing for an AI-discovered molecule and the legal challenges it presents for inventor attribution.

**Module 9: IP Due Diligence in Mergers & Acquisitions**

- Conducting a Risk-Based IP Audit for a target biotech company pre-acquisition, focusing on validity, FTO, and ownership.

- Identifying and remediating Title Defects and gaps in the chain of assignment from inventors and institutions.
- Assessing the value and enforceability of the target's existing patent portfolio and license agreements.
- Structuring IP-related representations, warranties, and indemnities in M&A transaction documents.
- Case Study: Performing a simulated IP Due Diligence on a synthetic biology startup being acquired by a major pharmaceutical company.

**Module 10: Licensing, Technology Transfer, and Commercialization**

- Drafting and Negotiating key clauses in an exclusive license agreement, including field of use, diligence, and termination.
- Structuring Royalty Stacks and Milestone Payments in complex, multi-party license agreements.
- Addressing Anti-Trust and Competition Law considerations in licensing and patent pooling.
- Strategies for successful university-to-industry technology transfer and managing Bayh-Dole Act obligations.
- Case Study: Analysis of the original Cohen-Boyer recombinant DNA patent licensing strategy and its impact on the industry.

**Module 11: Biotech Patent Litigation and Enforcement**

- The mechanics of a Patent Infringement Lawsuit from complaint filing to discovery and claim construction
- Strategies for seeking and defending against Preliminary Injunctions to stop infringing activity.
- Methods for calculating Lost Profits and Reasonable Royalty damages in biotech cases.
- Utilizing Mediation and Arbitration to resolve high-stakes disputes.
- Case Study: Examining the litigation strategy and outcome in AstraZeneca and the Forxiga Diabetes Drug patent challenge.

**Module 12: IP Valuation and Financial Strategy**

- The three main methodologies for IP Valuation
- Leveraging IP as Collateral for debt financing and managing the associated security interests.
- Communicating the Strategic Value of the patent portfolio to investors, boards, and financial markets.
- Using Patent Landscaping and Competitive Intelligence to benchmark portfolio strength against peers.
- Case Study: Developing a patent valuation report for a hypothetical Series B funding round for a cell therapy company.

**Module 13: Ethical and Socio-Political IP Challenges**

- Addressing the global debate on Compulsory Licensing for public health crises and its impact on drug pricing.
- The legal and ethical management of Biopiracy and access/benefit-sharing for genetic resources
- Patenting challenges in Green Biotechnology and sustainable agriculture.
- The role of patents in fostering innovation while addressing global equity and access to medicines.
- Case Study: Analysis of the ethical and legal challenges presented by patents on HIV/AIDS drugs in developing countries.

**Module 14: Protecting Trade Secrets and Know-How**

- Implementing robust internal systems and policies for Trade Secret Protection across the R&D and manufacturing lifecycle.

- Legal mechanisms for trade secret protection
- Distinguishing between non-confidential Know-How and legally protectable Trade Secrets.
- Strategies for protecting proprietary Manufacturing Processes
- Case Study: A review of the duPont v. Kolon Industries trade secret theft case and the punitive damages awarded.

**Module 15: Future-Proofing Biotech IP Strategy**

- Monitoring and adapting to Legislative Shifts in patent law
- Preparing for the impact of Quantum Computing on encryption and trade secret security.
- Integrating IP Management Software and AI tools for patent searching and portfolio monitoring.
- Developing an agile, jurisdictionally flexible IP strategy for novel platform technologies.
- Case Study: Discussion of 10x Genomics DNA analysis patent clashes and the strategies for defense in multi-jurisdictional disputes.

**Training Methodology**

The course employs an Advanced, Practical, and Case-Centric training methodology:

1. Expert-Led Lectures.
2. In-Depth Case Studies.
3. Interactive Workshops.
4. Strategic Templates.
5. Q&A with Practitioners.

**Register as a group from 3 participants for a Discount**

**Send us an email: info@fineskilltrainingcenter.org or call** +254769199797

**Certification**

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

**Tailor-Made Course**

We also offer tailor-made courses based on your needs.

**Key Notes**

**a.** The participant must be conversant with English.

**b.** Upon completion of training the participant will be issued with an Authorized Training Certificate

**c.** Course duration is flexible and the contents can be modified to fit any number of days.

**d.** The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

**e.** One-year post-training support Consultation and Coaching provided after the course.

**f.** Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

## Upcoming Scheduled Sessions

| Start Date | End Date | Location | Price |
|---|---|---|---|
| **23 Nov 2026** | 04 Dec 2026 | Online | $2,000 |
| **23 Nov 2026** | 04 Dec 2026 | Physical | $3,000 |
| **23 Nov 2026** | 04 Dec 2026 | Physical | $6,000 |
| **23 Nov 2026** | 04 Dec 2026 | Physical | $6,000 |
| **23 Nov 2026** | 04 Dec 2026 | Physical | $12,000 |
| **23 Nov 2026** | 04 Dec 2026 | Physical | $9,000 |
| **23 Nov 2026** | 04 Dec 2026 | Physical | $12,000 |
| **23 Nov 2026** | 04 Dec 2026 | Physical | $12,000 |

Ready to enroll or request a customized program? Book online or contact us:

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