Advanced Biopharmaceutical Intellectual Property Strategy Training Course

Professional Development Training Course Outline

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

Course Introduction

The rapidly evolving landscape of biopharmaceutical innovation demands a sophisticated and proactive approach to Intellectual Property. In a sector where a single novel biologic can represent billions in future revenue, the difference between market dominance and obsolescence often lies in the strength and strategic management of a company's patent portfolio Advanced Biopharmaceutical Intellectual Property Strategy Training Course is meticulously designed for legal and R&D professionals who need to move beyond foundational IP concepts and master the cutting-edge strategies, including biosimilar defense, inter partes review, and global patent harmonization, essential for securing and maximizing the value of biologics, gene therapies, and precision medicine.

This course delves deep into the confluence of scientific breakthroughs and complex regulatory frameworks, providing actionable insights into patent prosecution across major jurisdictions like the USPTO, EPO, and JPO. Participants will gain expertise in constructing impregnable freedom-to-operate positions, executing successful IP due diligence for M&A and licensing, and navigating the intricacies of Hatch-Waxman and BPCIA litigation. By focusing on real-world case studies involving high-stakes biotech conflicts, this training ensures that attendees are equipped with the strategic IP intelligence necessary to drive competitive advantage, secure investment, and protect the next generation of life-saving pharmaceutical innovations.

Programme Curriculum

Advanced Biopharmaceutical Intellectual Property Strategy Training Course

Introduction

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Course Objectives

1. Master the latest biosimilar and biobetter IP defense strategies under the BPCIA
2. Develop sophisticated global patent prosecution strategies for monoclonal antibodies and cell and gene therapies.
3. Design effective Freedom-to-Operate analyses tailored to precision medicine and companion diagnostics.
4. Navigate the complexities of inter partes review and other PTAB proceedings in the biotech context.
5. Execute comprehensive IP due diligence for high value biopharma mergers and acquisitions and Venture Capital investments.
6. Strategically leverage Supplementary Protection Certificates and patent term extensions across global markets.
7. Understand and mitigate risks related to AI-driven drug discovery and data exclusivity claims.
8. Formulate winning strategies for Hatch-Waxman litigation and managing the Orange Book listing.
9. Address ethical and legal challenges in CRISPR-Cas9 and other genome editing IP disputes.
10. Implement robust strategies for protecting trade secrets and know-how alongside patents in manufacturing.
11. Structure and negotiate complex biotech licensing agreements and joint development collaborations.
12. Analyze the impact of evolving patent eligibility standards on diagnostic IP.
13. Develop a future-proof IP portfolio that aligns with long-term corporate R&D and commercialization goals.

Target Audience

1. In-House IP Counsel and Attorneys in Biotech and Pharmaceutical companies.
2. IP Portfolio Managers and Strategists.
3. Patent Agents and Patent Examiners.
4. Chief Legal Officers and General Counsel.
5. Business Development and Licensing Professionals in Life Sciences.

6. Senior R&D Scientists and Drug Developers.
7. Venture Capitalists and Investment Bankers.
8. Litigation Attorneys and Experts.

Course Modules

Module 1: Foundational IP in Modern Biologics

- Distinguishing IP needs for small molecules vs. biologics
- The role of sequence claims and deposit requirements in biologics patenting.
- Freedom-to-Operate in crowded therapeutic areas
- Navigating the Trilateral Offices for harmonization.
- Case Study: Analyzing the seminal differences in patent claims for an early blockbuster biologic like Humira.

Module 2: Advanced Biologic Patent Prosecution Strategy

- Drafting claims for product-by-process and manufacturing methods protection.
- Effective strategies for divisional and continuation applications to extend patent life.
- Responding to written description and enablement rejections for novel biologics.
- Utilizing experimental data and declarations to overcome obviousness challenges.
- Case Study: Review of successful prosecution strategies for securing broad claims on a novel bispecific antibody.

Module 3: Cell and Gene Therapy (CGT) IP

- Specific IP challenges for AAV vectors, CAR-T cell therapies, and gene editing.
- Claiming therapeutic methods, dosing regimens, and patient selection diagnostics.
- Managing inventorship disputes in complex academic-industry CGT collaborations.
- Protecting next-generation delivery and manufacturing platforms for CGT.
- Case Study: The Kymriah IP landscape and its interaction with academic licensing.

Module 4: The CRISPR IP Wars and Genome Editing

- Deep dive into the CRISPR-Cas9 inventorship and priority disputes
- Strategies for claiming specific Cas-variants, delivery systems, and off-target mitigation.
- Navigating the ethical and public perception challenges in genome editing IP.
- Claiming use in in vivo vs. ex vivo therapeutic applications.
- Case Study: Comparative analysis of granted patents and denied claims in the wake of the major CRISPR rulings.

Module 5: Strategic Biosimilar Defense under the BPCIA

- Mastering the "Patent Dance" procedures and strategic decision points.
- Analyzing the timing and selection of patents for BPCIA litigation.
- The role of interchangeability and its impact on IP value and market access.
- Developing offensive and defensive strategies for the safe harbor.
- Case Study: Examining the patent landscape and subsequent litigation surrounding Enbrel and its biosimilars.

Module 6: PTAB and Post-Grant Review in Biopharma

- Strategic use of Inter Partes Review to challenge competitor patents.
- Defending key patents against IPR petitions
- Impact of the Fintiv factors on discretionary denial in biopharma IPRs.
- Coordination of district court litigation and concurrent PTAB proceedings.
- Case Study: An IPR proceeding that successfully invalidated key claims on a drug formulation patent.

Module 7: Hatch-Waxman and Small Molecule Strategy

- Reviewing the basics of Orange Book listing, Paragraph IV certifications, and 30 month stays.
- Advanced techniques for extending exclusivity via new formulations and uses.
- The role of pediatric exclusivity and orphan drug designation in lifecycle management.
- Strategic timing of patent expiry and regulatory exclusivities.
- Case Study: The long-running Nexium litigation involving polymorph and formulation patents.

Module 8: IP Due Diligence for M&A and Licensing

- Conducting a rapid and effective IP audit on a target company's portfolio.
- Identifying "red flags" and gaps in chain-of-title for critical assets.
- Valuation methodologies for IP assets in a biotech startup acquisition.
- Structuring representations and warranties related to IP in the M&A agreement.
- Case Study: Analyzing the IP risks and rewards in a major Big Pharma acquisition of a clinical-stage biotech company.

Module 9: Global Patent Term Extension

- Criteria and application process for Patent Term Extension in the US.
- Maximizing the duration of Supplementary Protection Certificates in the EU.
- Comparing global strategies for regaining patent life lost during regulatory approval.
- The intersection of PTE/SPC with pediatric studies and market authorization.
- Case Study: A comparative analysis of PTE/SPC filings for a single drug in the US and Europe.

Module 10: Trade Secrets and Know-How Protection

- Identifying protectable trade secrets in biomanufacturing and process optimization.
- Implementing internal controls and employee training to prevent trade secret misappropriation.
- The interplay between trade secret protection and public patent disclosure.
- Litigation strategies under the Defend Trade Secrets Act
- Case Study: A recent high-profile case involving biomanufacturing process trade secrets theft.

Module 11: Protecting AI-Generated IP and Data Exclusivity

- Addressing inventorship challenges when AI contributes significantly to drug discovery.
- Protecting machine learning models and proprietary training data as IP.
- Strategies for leveraging and protecting regulatory data exclusivity
- The challenge of patent eligibility for software-driven diagnostic algorithms.
- Case Study: Examining a patent claiming a novel compound identified by an AI platform.

Module 12: IP in Diagnostic and Precision Medicine

- Navigating the Mayo/Alice framework for diagnostic method patents.
- Strategies for drafting claims to overcome patent eligibility rejections.
- IP protection for companion diagnostics and personalized therapeutic regimens.

- Securing IP for biomarkers and screening methods.
- Case Study: A detailed review of successful patent strategies following the Ariosa v. Sequenom ruling.

Module 13: Drafting and Negotiating Biopharma Licenses

- Key terms in Exclusive vs. Non-Exclusive and Field-of-Use licensing agreements.
- Structuring milestone payments, royalties, and sublicensing provisions.
- Negotiating terms for enforcement and indemnification in a joint venture.
- Addressing termination clauses and the fate of IP upon contract breach.
- Case Study: Deconstructing a complex academic-industry license for a novel therapy.

Module 14: Global IP Portfolio Management & Budgeting

- Developing an IP budget that aligns with clinical trial phases and Go/No-Go decisions.
- Strategic abandonment and maintenance of non-core patents to optimize cost.
- Utilizing Patent Cooperation Treaty and national phase entry for global coverage.
- Implementing portfolio mapping to identify white space and competitive gaps.
- Case Study: A company's strategic decision to abandon IP in a key region due to high maintenance costs and low market potential.

Module 15: Litigation Trends and Future IP Risk

- Analysis of recent landmark Federal Circuit and Supreme Court rulings in biotech.
- Forecasting the impact of global legislative changes on biotech patenting
- Developing proactive strategies against patent trolls and non-practicing entities
- Integrating IP risk management into corporate governance structures.
- Case Study: Review of a recent high-stakes biotech infringement trial and the jury's decision on willful infringement.

Training Methodology

This program utilizes a highly interactive and practical methodology designed for advanced professionals:

- Case Study-Driven Learning.
- Expert-Led Lectures.
- Interactive Workshops & Role-Playing.
- Q&A/Discussion Forums.
- Tools & Templates.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.com 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
07 Sep 2026	18 Sep 2026	Online	$4,000
14 Sep 2026	25 Sep 2026	Online	$4,000
21 Sep 2026	02 Oct 2026	Online	$4,000
28 Sep 2026	09 Oct 2026	Online	$4,000
05 Oct 2026	16 Oct 2026	Online	$4,000
12 Oct 2026	23 Oct 2026	Online	$4,000
19 Oct 2026	30 Oct 2026	Online	$4,000
26 Oct 2026	06 Nov 2026	Online	$4,000

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