

# Pharmaceutical Patent Law Fundamentals

## For Scientists, Managers and Regulators



**Day:** Thursday, December 12, 2013 **Time:** 11:00 a.m.–12:30 p.m. (ET)

**Location:** Your Computer **Offering #** 1312-212 **Priority Code:** 520 (Available On-Demand starting 12/13/13)

### WHO SHOULD ATTEND

This introductory 90-minute accredited training webinar introduces the fundamentals of pharmaceutical patent law to professionals in the public and private sectors involved in the areas of drug development and approval. These professionals include academic researchers and scientists, such as faculty, post-doctoral fellows and graduate students, physicians, engineers, patent lawyers, and regulatory personnel from pharmaceutical and biotechnology industries, universities, and federal regulatory agencies such as the FDA, technology transfer and business managers, venture capitalists, and policy makers.

### LEARNING OBJECTIVES

Upon completion of this training, you will be able to:

- Explain the constitutional and policy bases for patents
- Describe the various sections (“anatomy”) of a patent
- Discuss the major requirements for patenting an invention
- Explain patent challenges under the Hatch-Waxman Act as they relate to brand and generic drugs
- Discuss the impact of recent Supreme Court cases on drug development

### COURSE DESCRIPTION

The major goal of this introductory course is to provide fundamental concepts in patent law to a broad audience, as they relate to pharmaceuticals. Patent law uses an archaic style and language to describe an invention (i.e., a patent); commonly used words, such as “novelty”, “anticipation”, “obviousness”, and “claims” have special meaning (“terms of art”) in patent law. Therefore, this course will also explain such patent terminology to enable better understanding of patent law concepts presented in the course.

The first module describes the major components of a patent document and how the invention is incorporated into this document. Second module provides a historical perspective, along with provisions for generic companies to challenge patents covering brand name drugs. Topics such as patent validity and infringement are included in this module. The third module discusses key pharmaceutical cases decided by the Supreme Court that could have a major effect on drug development.

#### Review of Learning Objectives

##### Module 1: Anatomy of a Patent Document

- Title
- Abstract
- Summary
- Diagrams (Figures)
- Specifications
  - Enablement
- Claims

##### Module 2: Hatch-Waxman Act

- Introduction
  - Balancing Innovation and Consumer Health Care Costs
  - Safe Harbor Provisions
- Provisions for Challenging Patents
  - Validity
  - Infringement

##### Module 3: Impact of Case Law on Drug Development

- Patentable Subject Matter
- Safe Harbor Provisions
- Obviousness

##### Question and Answer Session

### TUITION AND REGISTRATION

**TUITION\***– **Single Rate:** U.S.\$295.00 per person **Group Rate:** U.S.\$245.00 per person\*\*

Register at [www.cfpa.com](http://www.cfpa.com). Enter **Course Offering #1312-212** into **Quick Jump**. To register use **Priority Code: 520**.

For Questions and Information call Customer Service at 732-613-4500.

**Please Note:** Multiple participants are not authorized to share access provided to a single registrant, a single dedicated seat license must be purchased for each individual. CfPA reserves the right to cancel access or collect the group rate payment if this requirement has been violated. Only registered participants will receive accreditation.

**System Requirements:** PC-based attendees: Windows(R) 7, Vista, XP or 2003 Server/Macintosh(R)-based attendees: Mac OS(R) X 10.4.11 (Tiger(R)) or newer

For more information see reverse side ⇨



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## COURSE DIRECTORS

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### Srikumaran Melethil, Ph.D., J.D.

Srikumaran Melethil, Ph.D., J.D., is President and CEO, Law and Science Consulting (Springfield, OH), Professor Emeritus, University of Missouri-Kansas City (Schools of Pharmacy and Medicine) and Of Counsel, Fraser Clemens Martin & Miller, LLC, Perrysburg, OH, where his legal practice focuses on patent prosecution and infringement analysis in the area of pharmaceutical sciences.

Dr. Melethil is both a pharmaceutical scientist and a registered patent attorney. His scientific expertise covers the areas of pharmacokinetics, drug delivery, clinical pharmacology and drug analysis; he has published extensively in these areas. In the legal arena, he has published on the regulation of dietary supplements, World Anti-Doping Agency inclusion criteria for prohibited substances, and drug patent litigation arising under the Hatch-Waxman Act. He has presented short courses in patent law to graduate students at several pharmacy schools in the United States and Canada.

### Raj Bawa, MS, PhD

Raj Bawa, MS, PhD is a Patent Agent, Bawa Biotech LLC (Ashburn, VA); Adjunct Professor, Biology Department, Rensselaer Polytechnic Institute (Troy, NY); Scientific Advisor, Teva Pharmaceuticals, Ltd. (Israel); Co-chair, Nanotechnology Subcommittee, American Bar Association (Chicago, IL).

Dr. Raj Bawa is President of Bawa Biotech LLC. He is a biochemist and microbiologist by training as well as a registered patent agent licensed to practice (since 2002) before the US Patent and Trademark Office (PTO). He specializes in all aspects of biotechnology, chemical, nanotechnology and pharmaceutical patent law, including prosecution, patent strategy, application drafting, prior art searching, freedom-to-operate searching and technology research opinions. Dr. Bawa is an Adjunct Professor of Biology at Rensselaer Polytechnic Institute in Troy, New York as well as an Adjunct Professor of Natural and Applied Sciences at Northern Virginia Community College. He has hands-on bench experience, in biochemistry, microbiology and nanomedicine. He is Scientific Advisor to Teva Pharmaceutical Industries, Ltd. (Israel). He was previously employed as Patent Legal Advisor at Sequoia.

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## WHO WE ARE

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The Center for Professional Advancement (CFPA) is the largest accredited technical training organization in the world with a curriculum of approximately three hundred and fifty short courses in 18 industries including Pharmaceutical, Biotechnology, Medical Device, Chemical, Cosmetics, Food and more.

Since our founding in 1967, we have successfully trained nearly a half million people worldwide in topics ranging from basic and introductory concepts to new advances and cutting-edge technology, and current U.S. and European regulations. CFPA courses are offered in a variety of formats – Public offering, Client Site and Online – to fit you or your company's training needs.

For more information visit our website at [www.cfpa.com](http://www.cfpa.com)

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## ACCREDITATIONS

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The Center for Professional Advancement has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500 McLean, VA 22102. In obtaining this approval, The Center for Professional Advancement has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. The Center for Professional Advancement is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEUs will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal training and a minimum score of 70% on the assessment. The Center for Professional Advancement is therefore authorized to offer IACET CEUs at a rate of .1 CEU per contact hour (rounded to the nearest tenth) for its programs that qualify under the ANSI/IACET Standards.

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## COURSES OF INTEREST

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- **Applied Project Management Fundamentals**  
course ID# 2529
- **INDs/NDAs/CTDs**  
course ID# 448
- **International Patent Law**  
course ID# 2100
- **Patent Law**  
course ID# 520
- **Pharmaceutical Process Development**  
course ID# 1358

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## TERMS AND CONDITIONS

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**\*Payment:** Tuition payable in US funds net of all charges. Payment is due at time of registration in the form of a credit card. Please contact CFPA's Customer Service for other payment options.

**\*\*Group Rate:** The Group Rate is for two or more enrollments, up to five registering from the same company at the same time. For groups of six or more, please contact Customer Service for group pricing.

**Cancellations/No Show: "Live"**- Registrants may cancel up to two working days prior to the course start date and will receive a letter of credit to be used towards a future course up to one year from date of issuance. No credit will be issued for no-shows and/or cancellations less than two working days prior to the course. : **"On-Demand"**- No refund or credit will be issued for no-shows and/or cancellations of on-demand training courses. CFPA is not responsible for any outside related costs incurred by registrant's cancellation.

ID 2595