Pharma Symposium 2026

Pharmaceutical, Biotechnology & Chemical Patents — U.S., Europe, China & India

ORGANISERS

Khurana & Khurana

IIPRD

Carlson Caspers

Bonabry

Tee & Howe

- U.S. Pharmaceutical Patent Litigation: 2025–2026
- Key Federal Circuit Decisions and U.S. Patent Litigation Trends
- Building, Clearing, and Monetizing a Pharmaceutical Patent Asset in the Post-Amgen Era
- Lifecycle Management and Secondary Patents
- Recent Trends and Key Developments in European Pharmaceutical Patent Litigation
- European Regulatory and IP Update
- Patent Protection Strategies for Pharmaceutical and Biotechnology Innovations in China
- Pharmaceutical Patent Prosecution and Litigation Trends in India

Schedule	Venue
7–8 December 2026	**Park Hyatt Hyderabad**
9–10 December 2026	**Hilton Mumbai**

SYMPOSIUM BOOKLET

Contents

01 — OVERVIEW

About the Symposium

Global Pharmaceutical IP: Key Trends, Challenges, and Strategic Considerations

The global pharmaceutical industry is witnessing unprecedented change, driven by increasingly complex patent landscapes, evolving regulatory exclusivities, biosimilar competition, artificial-intelligence-driven drug discovery, and major legislative reforms across key markets.

As pharmaceutical innovation becomes more globalized, companies must navigate a sophisticated interplay of patent rights, regulatory protections, litigation risks, and commercialization strategies across multiple jurisdictions. For Indian pharmaceutical companies, understanding developments in the United States, Europe, and China is no longer optional — it is critical for successful global product development, market entry, lifecycle management, licensing, investment, and dispute resolution.

This intensive, advanced-level symposium has been designed specifically for experienced pharmaceutical IP professionals, in-house counsel, patent attorneys, R&D leaders, regulatory experts, and business executives who seek practical, commercially relevant insight into the latest global developments affecting pharmaceutical innovation and market exclusivity.

Through expert-led sessions, comparative legal analysis, real-world case studies, and strategic comprehensive understanding of the evolving pharmaceutical IP ecosystem and its discussion for implications will gain participants innovators, generic manufacturers, biosimilar developers, and investors.

> "AI, *patent cliffs, and biosimilar litigation are reshaping the pharmaceutical IP landscape — this symposium brings together the practitioners navigating it first-hand.*"

AT A GLANCE

Highlights & Who Should Attend

AI, patent cliffs, and biosimilar litigation are reshaping the pharmaceutical IP landscape. This symposium addresses the critical legal and strategic insights needed for sustained innovation and market leadership.

The Sector Faces Increasing Pressure From

- Intensifying generic and biosimilar competition
- Higher patent invalidation rates in major jurisdictions
- Increased scrutiny of pharmaceutical patent quality
- Growing reliance on regulatory exclusivities
- AI-driven innovation disrupting traditional drug discovery models
- Expanding biologics and advanced-therapy markets
- China's emergence as a major pharmaceutical innovation hub
- Cross-border patent enforcement and litigation complexities

Who Should Attend

- IP and patent management teams
- R&D scientists and technical experts
- Patent agents and practicing patent attorneys
- IP and pharmaceutical litigators Legal busine ss Professionals in the pharma, biotech, and chemical sectors.

REGISTRATION

Registration Fee

INDIAN DELEGATES

₹15,000

Per delegate

FOREIGN DELEGATES

$300

per delegate

PROGRAMME

Session Outline

Day 1

DEEP-DIVE ON U.S. PATENT STRATEGY

Session 1 — U.S. Pharmaceutical Patent Litigation: 2025–2026 Developments, Decisions, and Trends

9:30-11:00

Speaker: *Nate Louwagie, U.S. Attorney*

U.S. pharmaceutical patent litigation landscape has undergone consequential shifts over the the past two years — driven by landmark Supreme Court and Federal Circuit decisions, evolving Hatch-Waxman and ANDA practice, and intensifying antitrust scrutiny of brand-name lifecycle strategies. This session delivers a rigorous, current account of where U.S. pharmaceutical patent Litigation stands today

Part 1 — Litigation Landscape: Filing, Settlement, and Decision Trends (2025–2026)

- Statistical overview of ANDA and biologic litigation filing, settlement and trial trends
- District court forum dynamics
- Settlement structures: at risk launch trends, authorized generic economics, and negotiating leverage

Part 2 — U.S. Supreme Court and Federal Circuit Decisions: Practical Implication

- Hikima Pharmaceuticals USA Inc. V. Amarin Pharma, Inc. (U.S. Supreme Court June 2026): Unanimous reversal of the Federal Circuit on whether a skinny lapel plus p Lublin sentiments constitutes active inducement under 35 U.S.C. Section 271(b); carve-out strategies and practical lessons.
- In re Entresto (Fed. Cir 2025): written description and invalidity developments for drug-combination patents.
- Mybetriq Astellas v. Ascent (D. Del. 2026): claim construction for over active-bladder formulation and reduced food effect term construction.
- Obviousness based on clinical trial disclosures, and inherency arguments in formulation patents
- AI assisted prior art searching in ANDA litigation, and how courts are treating its reliability and scope

KEY TAKEAWAYS

• Supreme Court's Hikma decision raises the pleading bar for brand-side induced-infringement claims
• Federal Circuit decisions continue to shape litigation strategy
• The FTC's sustained Orange Book delisting campaign signals a new era of antitrust risk for routine lifecycle practices. Antitrust scrutiny after In re Amitiza.

— TEA BREAK · 11:00 – 11:15 —

Session 2 — The Changing Post-Grant Landscape at the USPTO: Updates and Insights for Generic and Biosimilar Developers

11:30 – 13:00

Speaker: Peter M. Kohlhepp, Carlson Caspers (U.S. Patent Attorney)

The post-grant challenge landscape at the U.S. Patent Office — spanning inter partes review (IPR), post-grant review (PGR), and ex parte reexamination (EPR) — has shifted significantly over the past year and continues to evolve rapidly. This session reviews the key changes, highlights emerging trends, and examines the case law shaping current practice. Attendees will leave with practical, up-to-date guidance on how to deploy post-grant challenges effectively as part of a generic or biosimilar development strategy.

.

Part 1 — How the Post-Grant Landscape Has Changed This Past Year

- Recent USPTO policy and rule changes affecting IPR institution rates
- The growing use of ex parte reexamination (EPR) as a strategic alternative
- Review of the data -- what the latest statistics reveal
- New Federal Circuit and district court decisions reshaping post-grant practice

Part 2 — Strategic Considerations and Case Study Updates

- Practical approaches to leveraging post-grant challenges within a broader patent strategy
- Case study updates

Part 3 — Future Outlook

- Legal challenges to USPTO policy changes affecting IPRs
- Prospects (and likelihood) of legislative action
- What developers should watch for going forward

KEY TAKEAWAYS

- Navigate the evolving post-grant landscape
- Stay ahead of critical case law-Gain insights into recent Federal Circuit and district court decisions shaping post-grant challenge strategy and practice.
- Strengthen generic & biosimilar strategies

— NETWORKING LUNCH · 13:00 –14:00

Session 3 — Biologics and Biosimilars: Review and update on recent case law

14:00 – 15:30

Speaker: Iain A. McIntyre Carlson Caspers (U.S. Patent Attorney)

This session examines the evolving U.S. biosimilars landscape under the BPCIA, with a focus on the legal and strategic issues affecting market entry and patent disputes. It will cover key aspects of the BPCIA framework, including exclusivity, the "Patent Dance," patent listing, infringement, injunctions, and launch timing. Recent landmark decisions will be discussed to illustrate developments in enablement, written description, claim construction, and patent eligibility.

Part 1. Brief review of Biologics Price Competition and Innovation Act (BPCIA)

- Exclusivity
- "Patent Dance"
- Patent listing/"Purple Book"
- Infringement and Injunctions
- Launch timing

Part 2. Case Updates

- Regeneron v. Mylan (EYELEA) (2025)
  - The most significant BPCIA case to have come out of the Fed. Cir, this family of decisions covers many issues including personal jurisdiction, obviousness-type double patenting, written description, and claim construction.
- Enablement and written description (35 U.S.C. § 112)
  - Background set by Amgen v. Sanofi (2023), a U.S. Supreme Court Case addressing the scope of enablement under 35 U.S.C. § 112 for antibodies
  - Seagen v Daiichi Sankyo (2025) (Fed. Cir). The application described more than 47 million possible tetrapeptides, and the claims at issue covered an 81-member subgenus of the 47 million. The court found the subgenus was not enabled as the specification failed to particularly point a person of skill to the claimed subgenus.
  - Teva v. Eli Lilly (2026) (Fed. Cir.) The Court overturned a lower court's finding that the patents were invalid for lack of enablement and written description. The Court distinguished from Seagen based on the use of a known genus of antibodies for a particular therapeutic purpose.
- Patent eligible subject matter (35 U.S.C. § 101)
  - Regenxbio v Sarpeta addressed how different a cell has to be from one existing in nature in order to qualify as patentable matter under 35 U.S.C. § 101

KEY TAKEAWAYS

- Master the BPCIA framework & "Patent Dance"
- Understand the latest biosimilar case law
- Navigate §101, §112 & patentability risks
- Develop effective biosimilar launch strategies

— TEA BREAK · 15:30 – 16:00 —

Session 4 — From Product Selection to U.S. Launch: Integrated Patent, FTO, and Lifecycle-Management Strategy

16:00 - 17:30

Speaker: Gary J. Speier, Carlson Caspers (U.S. Patent Attorney)

For in-house patent managers, a successful U.S. pharmaceutical launch depends on coordinated decisions concerning product selection, patent protection, freedom to operate, and commercialization. Using a small-molecule pharmaceutical product as a running case study, this session presents a practical framework for managing those decisions from initial evaluation through U.S. market entry.

Part 1 — Product Selection and Portfolio Design

- Align patent strategy with the intended commercial product, regulatory pathway, development timeline, and competitive landscape
- Build commercially meaningful protection around compounds, processes, intermediates, forms, formulations, combinations, and methods of use
- Decide which innovations should be patented, maintained as trade secrets, licensed, or designed around

Part 2 — FTO as a Continuing Process

- Begin FTO during product selection and update it through a stage-gate process at key development and commercialization milestones
- Map third-party claims to the proposed product, manufacturing process, formulation, labeling, and commercial activities
- Convert the analysis into practical options: proceed, redesign, license, challenge, delay, or discontinue

Part 3 — Lifecycle Management and Commercialization

- Coordinate patent protection and FTO with product development, regulatory strategy, sourcing, partnering, and launch planning
- Evaluate proprietary portfolio strength and third-party patent risk together during licensing, investment, and due diligence
- Use a portfolio-coverage map and patent-risk matrix to communicate assumptions, alternatives, timing, and residual risk to management

KEY TAKEAWAYS

- Patent strategy should begin with the intended commercial product and business objective—not merely the invention disclosure
- FTO should be treated as a staged management process, not a one-time pre-launch search
- Effective in-house patent management converts claim-level analysis into timely, actionable business decisions

Session Outline

Day 2

EUROPE, CHINA & INDIA PERSPECTIVE

Session 5 — Recent Trends and Key Developments in European Pharmaceutical Patent Litigation

09:30 – 11:00

Speaker: Dr. Alexander Wittkopp, Patent Attorney & European Patent Litigator

An in-depth review of the latest pharmaceutical patent decisions across Europe, examining how the EPO, national courts, and the CJEU continue to shape patent enforcement and validity challenges — with practical insight for innovator, generic, and biosimilar companies.

KEY TAKEAWAYS

- Convergence and divergence in national court interpretations of pharmaceutical patent law•
- Developments in Supplementary Protection Certificate (SPC) jurisprudence and their impact on exclusivity strategy
- Emerging trends in validity, infringement, preliminary injunctions, and launch-at-risk Litigation

— TEA BREAK · 11:00 – 11:15 —

Session 6 — European Regulatory and IP Update: Data and Market Exclusivity, Skinny Labelling & Cross-Border Patent Litigation

11:30 – 13:00

Speaker: Dr. Sarah Salaschek, Attorney at Law & European Patent Litigator

A deep dive into data and market exclusivity, skinny labelling, and cross-border patent litigation, including the new legal framework under the European Pharma Package — the most significant revision of EU pharmaceutical legislation in over 20 years.

Covers

• The current legal framework for innovative drugs in Europe, and strategic considerations for Innovators and bio similar developers

• Carve-out strategies under the current EU framework for skinny labelling, and recent case law

- The CJEU's BSH/Electrolux decision and its implementation before national courts and the Unified Patent Court

— NETWORKING LUNCH · 13:00 – 14:00 —

Session 7 — Patent Protection Strategies for Pharmaceutical and Biotechnology Innovations in China

14:00 – 15:30

Speaker: Toby Mak, China Patent Attorney

Practical patent-protection strategies for pharmaceutical and biotechnology inventions, recent legislative and judicial developments, and the growing impact of China's patent linkage system, patent term adjustment and extension, and drug data exclusivity on lifecycle management and market entry.

KEY TAKEAWAYS

- Claim strategies for new crystal form, second medical use, dosage regimen, and biologics under CNIPA Examination practice.
- "Method of treatment" claim formats — Swiss-type and purpose-limited product claims
- Polymorphs, salts, and fixed-dose combinations, and evidentiary requirements for unexpected technical effects
- China's patent linkage system compared with the U.S. Hatch-Waxman framework
- Patent term adjustment and extension, and the current drug data exclusivity framework

— TEA BREAK · 15:30 – 16:00 —

Session 8 — Pharmaceutical Patent Prosecution and Litigation Trends in India

16:00 – 17:30

Speaker: Tapan Shah, Indian Patent Attorney

India remains one of the world's most influential pharmaceutical markets, serving as a global hub for generic drug manufacturing while maintaining a unique patent framework that balances innovation and public health. This session examines the latest developments in pharmaceutical patent prosecution, litigation, and enforcement in India.

KEY TAKEAWAYS

- Recent trends in pharmaceutical patent examination before the Indian Patent Office, and patentability challenges under Section 3(d)
- Patent protection strategies for incremental innovations, new forms, formulations, and polymorphs
- Recent High Court and Supreme Court decisions shaping pharmaceutical patent jurisprudence, and evolving standard for interim injunctuions
- Launch-at-risk litigation trends, freedom-to-operate assessments, and generic market-entry planning

Participants will gain a comprehensive understanding of India's evolving pharmaceutical patent landscape, including key prosecution challenges, litigation trends, enforcement strategies, and commercial considerations affecting pharmaceutical innovation and generic competition — with actionable insight for patent, regulatory, and market-entry strategy in India.

About the Organisers

Trusted leaders in IP and legal innovation, IIPRD and Khurana & Khurana bring decades of global experience across patent strategy, litigation, and commercialisation — with a presence across Asia, the US, and the GCC, serving clients from startups to Fortune 100 companies.

K&K KHURANA & KHURANA
An ISO 9001:2015 | ISO/IEC 27001:2022 Certified Firm

Khurana & Khurana (K&K) is a leading full-service law firm in India, ranked and recommended by international publications including Chambers & Partners, Legal 500, Managing IP, IAM, Asia IP, RSG, Acquisition INTL, Corp INTL, and Benchmark Litigation.
The firm operates through offices across India, South-East Asia, United States, UAE/GCC. K&K, with a team of over 350 professionals focuses comprehensively on Intellectual Property, Corporate Transactions and Disputes

IIPRD
An ISO 9001:2015 Certified Firm

IIPRD is a well-established Intellectual Property Asset Management firm specializing in comprehensive patent support, litigation support, and licensing/commercialization mandates for global corporates, law firms, and licensing entities.

The firm focuses extensively on IP audits, due-diligence exercises, and I valuations, alongside patent illustration and IDS preparation, docketing, and a full range of patent searches patentability, validity, freedom-to-operate and landscape analytics making it a one-stop solution for complex, cross jurisdictional IP requirement.

Bonabry

Bonabry is a boutique intellectual property and patent law firm with offices in Germany and France, recognized for its strategic, client-focused approach to complex IP matters. The firm brings together a team of experienced patent attorneys and IP litigators with deep expertise in the pharmaceutical, biotechnology, chemical, and life sciences sectors. Bonabry is particularly renowned for advising generic pharmaceutical companies on product launches in challenging patent landscapes, including freedom-to-operate assessments, launch strategies, patent litigation, and proceedings before German courts and the Unified Patent Court (UPC). The firm also advises on pharmaceutical regulatory law, competition and advertising law, trademarks, and data protection matters.

CARLSON CASPERS

Founded in 2003 and based in Minneapolis, Carlson Caspers is known for excellence in intellectual property litigation and counseling, serving clients from individuals to Fortune 500 companies. Its attorneys — scientists, engineers, chemists, technologists, and pharmacists — are recognized by the American College of Trial Lawyers, Chambers USA, IAM Patent 1000, IP Stars, Best Lawyers, and Super Lawyers.

TEE & HOWE 天昊联合

Tee & Howe Intellectual Property Attorneys, established in 1995, is one of China's pioneering intellectual property firms licensed by the China National Intellectual Property Administration (CNIPA) to handle both domestic and international IP matters. The firm provides comprehensive IP services across patents, trademarks, copyrights, licensing, prosecution, enforcement, and litigation. . Recognized for its technical excellence and global outlook, Tee & Howe is an active member of leading international IP organizations, including AIPPI, INTA, FICPI, LES, AIPLA, and prominent Chinese IP associations

Our Faculty

Gary J. Speier

PATENT ATTORNEY, CARLSON CASPERS

A registered U.S. patent attorney focused on the life sciences sector, Gary is a patent litigator who conducts pre-suit investigations, IP valuations, and due diligence, and provides freedom-to-operate opinions and patent-prosecution strategy across domestic and international jurisdictions. He has been involved in numerous post-grant proceedings before the USPTO across medical devices, drug delivery systems, and pharmaceuticals.

Peter Kohlhepp

PATENT ATTORNEY,CARLSON CASPERS

Peter practices in intellectual property with a focus on high-stakes patent litigation and post-grant proceedings, spanning medical devices, automotive technology, pharmaceuticals, and telecommunications. He has extensive experience before the USPTO's Patent Trial and Appeal Board, including frequently delivering successful oral arguments.

Nate Louwagie

EQUITY PARTNER, CARLSON CASPERS

Nate is a registered patent attorney with experience counseling clients from various industries in intellectual property disputes. He is a zealous advocate who takes pride in identifying a winning argument and clearly articulating that argument in briefing and oral arguments. He also enjoys managing complex cases with many interrelated factual and legal issues.

Iain A. McIntyre

EQUITY PARTNER, CARLSON CASPERS

Iain dedicates most of his time to high technology patent issues. He conducts pre-suit investigations and IP due diligence investigations and provides freedom-to-operate and opinions relating to infringement and validity, as well as litigating patent infringement cases. Iain also drafts and negotiates patent licenses and develops patent procurement and patent prosecution strategies. He has practiced before the USPTO for over 25 years and has extensive experience preparing and prosecuting patent applications. He has also been involved in many post-grant procedures in front of the PTO. For the past several years, his work has been involved in telecommunications, including cellular base stations and antennas, distributed antenna systems, Wi-Fi and RF systems and components, and fiber optical communications systems.

Dr. Alexander Wittkopp

PARTNER, BONABRY

As a partner and patent attorney at Bonabry (based in the firm's office in Hamburg, Germany), he represents his clients in the areas of German, European, and US intellectual property law, including patent prosecution, oppositions, nullity and infringement proceedings, as well as preparing relevance- and validity-opinions in the field of general chemistry, biochemistry, and pharmaceuticals. Alexander is a qualified German and European Patent Attorney and a European Patent Litigator, as well as a US Patent Agent, and for more than 20 years Alexander assists his Indian clients in the assessment of the patent situation of their APIs, syntheses, and generic products and biosimilars, if necessary, he supports them in identifying approaches to circumvent possibly crucial proprietary rights, and he represents Indian companies in opposition proceedings before the EPO as well as in revocation actions before the German Patent Court and the Unified Patent Court.

Dr. Sarah Salaschek

ATTORNEY AT LAW & EUROPEAN PATENT LITIGATOR, BONABRY

Sarah is attorney at law and counsel at Bonabry. She advises clients in the pharmaceutical industry and represents them in court. Her practice covers all questions of intellectual property law as well as related questions on pharmaceutical law, healthcare advertising law, medical devices law and unfair competition law. Her particular focus is on pharma patents, SPCs and related regulatory issues, such as data and market exclusivity and carve-out possibilities. She regularly advises clients on launch strategies for their generic and biosimilar products and represents them before German courts as well as before the Unified Patent Court.

Before joining Bonabry, Sarah worked for several years in the life science / IP department of a major international law firm. This included a one-year secondment at one of the world's leading pharmaceutical companies.

Dr. Toby MAK

SENIOR COUNSELER/ PATENT ATTORNEY

Dr. Toby Mak is an experienced patent professional with over 10 years of expertise in patent and design law.
Deal finder for US investment firm for patent investment of USD10 million to 5 billion per deal
IPO - Vice Chair of the Asian Practice committee, and member of the Membership Committee of the IPO
AIPLA - past co-chair of the AIPLA's IP Practice in China committee and IP Practice in the Far East committee, and current AIPLA's representative at the US Bar Association/CNIPA Liaison Council ·
One of the authors of "Patent Law in Greater China"
Born and educated in Hong Kong with a PhD in chemistry
The only Chinese patent attorney working in a Beijing Chinese patent firm from Hong Kong ·
Trained under the UK system and took the UK CIPA examinations, and passed some of the papers
Responsible for publishing articles on China IP update for the UK CIPA Journal ·
Member of AIPLA, IPO, UK CIPA, INTA
Languages: Chinese (Mandarin and Cantonese), English

Tarun Khurana

CO-FOUNDING PARTNER, KHURANA & KHURANA / IIPRD

With over 23 years of experience across IP subject matters, Tarun is ranked among India's top patent practitioners by IAM 1000 and IAM 300 Strategists, focusing on patent portfolio management, litigation, valuation, and IP commercialization for clients ranging from startups to Fortune 5 companies.

Tapan Shah

INDIAN PATENT ATTORNEY

With more than 15 years of experience in patents and related IP rights, Tapan holds a Master's in Medicinal Chemistry from NIPER, Mohali, and has assisted Fortune 500 pharmaceutical and chemical companies, U.S. and European law firms, and in-house patent counsel on product and process development and commercialization.

Registration Details

Secure your place at Pharma Symposium 2026 — complete your delegate details and payment using the information below.

Delegate Fee Submission

We kindly request all participants to share the following information along with the delegate fee:

1. Full name
2. Organization
3. Designation
4. Complete address
5. Contact number & email ID

Payment Instructions

Please make the delegate fee payment via bank transfer or UPI using the details below.

Account Holder: IIPRD

Bank Name: Axis Bank Ltd.

Account No.-917020069762436

Branch: Alpha Commercial, Greater Noida

IFSC Code: UTIB0000624

Account Type: Current

Scan to pay via UPI

For Any Queries

Ms. Bhumika Tewari

Mobile: +91-8920269831

Telephone: +91-(120) 3132513

bhumika@khuranaandkhurana.com

conference@iiprd.com