# Pharma Symposium- 2025

Pharmaceutical, Biotechnology & Chemical Patents - U.S., Europe & India

- Patent strategies from Candidate Selection to Launch
- Post-grant challenges
- Litigation trends
- Valuation of pharma patents
- AI tools in FTO Clearances

| Schedule:                 |  |
|---------------------------|--|
| 22 -23 September<br>2025  | Hotel Taj Deccan,<br>Hyderabad                     |
| 24 - 25 September<br>2025 | Hotel Hilton<br>(International Airport),<br>Mumbai |

Organisers:

Khurana & Khurana



Carlson Caspers

Hamm & Wittkopp





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# PHARMA SYMPOSIUM 2025

#### About the

# Symposium





Explore how AI, evolving patent laws, and biosimilar litigation are redefining pharmaceutical innovation. This symposium addresses the urgent IP challenges shaping the future of the pharma and biotech industries.

AI is revolutionising drug discovery, while the pharmaceutical sector braces for a patent cliff from 2025 to 2030, when several blockbuster drugs will lose exclusivity. In this context, patents are not just protective tools but strategic assets. A deep understanding of the patent lifecycle and legal framework is essential for innovation and long-term growth.

The emergence of biosimilars raises urgent questions for innovators: how to protect biologics, navigate biosimilar entry, and manage litigation effectively. The "patent dance," FTO assessments, and the impact of these on cost and market access must now be central to every IP strategy.

Timely updates on the Hatch-Waxman Act and recent case laws are also crucial to staying compliant and competitive. These developments directly affect regulatory pathways and the ability to defend or challenge exclusivity.

This two-day symposium gathers global experts to discuss the latest in patent protection, litigation trends, and the role of AI in shaping IP strategy. With focused sessions for R&D professionals, legal teams, and business leaders, it aims to enable smarter, future-ready IP decisions.

The Symposium would also offer strong networking opportunities for the attendees to interact with the speakers and fellow delegates through a combination of roundtable discussions, networking lunches, Q&A with speakers so as to maximize the learning from the event.

# Highlights

### & Who should attend

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

#### What Sets This Symposium Apart:

- Global Scope: Insightful sessions covering developments across the U.S., Europe, and India
- Expert Faculty: Led by senior IP counsels, experienced litigators, and leading patent attorneys
- Practical Orientation: Featuring real-world case studies, strategic insights, and recent judgments
- Cross-Functional Relevance:
   Curated for professionals in Legal,
   R&D, Regulatory, and Business roles
- Emerging Trends: Deep dives into AI tools, biosimilar litigation, patent valuation, and more

#### 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-Business Professionals in the Pharma, Biotech, and Chemical sectors

# PHARMA SYMPOSIUM 2025

# Registration Fee

INDIAN DELEGATES: FOREIGN DELEGATES:

INR 15000 Per Delegate USD 300 Per Delegate

# Session Outline

### Deep-dive on U.S. Patent Strategy



#### 09:30 A.M. TO 11:00 A.M.

Speaker: Jennell Bilek (US Attorney)

#### **SESSION-1:** Latest on Hatch-Waxman

Explore current litigation strategies under Hatch-Waxman and BPCIA, and understand what they mean for generic and biosimilar companies

#### Key Takeaways:

- Paragraph IV litigation landscape and trends
- Recent court rulings
- Antitrust lawsuits



## 11:00 A.M. TO 11:15 A.M. TEA BREAK



#### 11:30 A.M. TO 1:00 P.M.

Speaker: Peter Kohlhepp (US Attorney)

#### **SESSION-2:** Grant Strategy for Biosimilars

Strategic use of Post-Grant Proceedings for Biosimilars. An overview of how IPRs, PGRs, and oppositions can be tactically used to challenge or defend biologic patents, and manage litigation risks.

#### Key Takeaways:

- Choosing IPR vs GPR
- PTAB Litigation Trends
- Real-world invalidation case studies



#### <u>01:00 P.M. TO 02:00 P.M.</u>

NETWORKING LUNCH



#### 02:00 P.M. TO 03:30 P.M.

Speakers: Jennell Bilek and Gary Speier (US Attorneys)

# <u>SESSION-3:</u> Biosimilars: Strategy from Selection to Launch

Explore the strategic lifecycle of biosimilars from a scientific, regulatory, and commercial lens

#### Key Takeaways:

- Reference product selection
- Regulatory harmonization
- Clinical, pricing, and launch strategy



03:30 P.M. TO 04:00 P.M. TEA BREAK



#### 04:00 P.M. TO 05:30 P.M.

Speaker: Gary Speier (US Attorney)

#### **SESSION-4:** AI Tools for FTO Clearances

Discover how software and AI tools are currently providing data-driven insights and streamlining FTO reviews and risk assessments.

#### Key Takeaways:

- AI tools in patent landscape analytics
- Automating clustering & risk scoring
- Use cases in pharma R&D

# Session Outline

## Deep-dive on U.S., Europe & India Patent Strategy



#### 09:30 A.M. TO 11:00 A.M.

Speaker: Gary Speier (US Attorney)

<u>SESSION-5:</u> Valuation of Pharma Intangible Assets.

Learn advanced valuation techniques critical for licensing, M&A, and internal decision-making. Pharma intangible assets include patents, trademarks, ANDAs, and NDAs.

#### Key Takeaways:

- Pharma-specific value drivers
- Cost, market, and income valuation models
- Legal defensibility of valuation



#### 11:30 A.M. TO 1:00 P.M.

Speaker: Dr. Alexander Wittkopp (Patent Attorney & European Patent Litigator)

SESSION-6: Trends, latest decisions and recent developments in European Court Cases

How the national courts and the Court of Justice shape the landscape of pharmaceutical patents in Europe.

#### Key Takeaways:

- Recent patent case laws in major EU jurisdictions, consistent and inconsistent decisions
- Latest national and central decisions around Supplementary Protection Certificates.
- Practical use of the Manufacturing and Export-Waiver – and its constraints



#### 01:00 P.M. TO 02:00 P.M. NETWORKING LUNCH



#### <u>11:00 A.M. TO 11:15 A.M.</u> <u>TEA BREAK</u>



#### 02:00 P.M. TO 03:30 P.M.

Speaker: Dr. Nils Kahlcke (Patent Attorney & European Patent Litigator)

<u>SESSION-7:</u> Introduction into the Unitary Patent System and its impact to Europe's pharmaceutical patent legal system.

#### Key Takeaways:

- Unified Patent Court Streamlined litigation process
- Unitary Patent System Latest Case Laws at the UPC Courts in the Pharma/Bio domains
- Recent decisions in Pharma domains issued by the EPO's Boards of Appeal



#### 04:00 P.M. TO 05:30 P.M.

Speakers: Tarun Khurana & Tapan Shah

<u>SESSION-8:</u> Indian Patent Prosecution Strategies and Litigation Trends.

An update on latest Pharma/Biotech Litigation/Opposition Cases in Indian Courts with key learnings.

#### Key Takeaways:

- Latest Relevant Case Laws in the Pharma/Bio domains
- Key outcomes from said cases and tests/standards laid out
- Major Patent Litigation Cases



03:30 P.M. TO 04:00 P.M. TEA BREAK

# AARMA SYMPOSIIIM 202

# About the Organisers:

# KK KHURANA & KHURANA





Trusted leaders in IP and legal innovation, IIPRD and Khurana & Khurana bring decades of global experience across patent strategy, litigation, and commercialization. With a presence across Asia, the US, and GCC, the firms deliver end-to-end legal and IP solutions to clients ranging from startups to Fortune 100s.

#### **IIPRD**:

IIPRD is a well-established Intellectual Property Asset Management Firm that specialises in providing comprehensive Patent Support Services, Litigation Support, and Licensing/Commercialization mandates to global corporates, law firms, and licensing entities. With a strong emphasis on practical, business-aligned IP solutions, IIPRD has become a trusted partner for organisations seeking high-quality, end-to-end patent and IP strategy support.

The firm also extensively focuses on conducting IP Audits, Due Diligence Exercises, and IP Valuations, offering a full spectrum of patent support services. These include patent illustration and IDS preparation support, docketing and paralegal assistance, as well as undertaking a wide range of patent searches—covering patentability, validity, freedom-to-operate (FTO), landscape analysis, and analytics. IIPRD also provides robust drafting, prosecution, and litigation support services, making it a one-stop solution for complex IP requirements across jurisdictions.

#### KHURANA & KHURANA:

Khurana & Khurana (K&K) is a leading full-service law firm in India, ranked and recommended by several reputed international publications including Chambers & Partners, Legal 500, Managing IP, IAM, Asia IP, RSG, Acquisition INTL, Corp INTL, and Benchmark Litigation.

The firm operates through exclusive offices in the United States, UAE/GCC, Malaysia, Sri Lanka, Thailand, Indonesia, Philippines, Bangladesh, Vietnam, Nepal, and Myanmar, and caters to both Indian and international clients—ranging from early-stage start-ups to Fortune 100 companies. Its team of over 330 professionals is spread across 10 offices in India.

K&K provides end-to-end legal solutions across all major practice areas, with a comprehensive focus on Intellectual Property, Commercial, Corporate & Company Law, Taxation, RERA/Property, TMT, Banking & Finance, Media & Entertainment, Employment & Labour Law, POSH, and Arbitration. The firm also has significant expertise in Corporate Compliance, Regulatory Advisory, and Secretarial Services.

K&K takes strong pride in its client-centric approach, prompt communication across departments, and flexibility to client needs, enabling it to consistently deliver results aligned with client objectives—at the right cost structure

# About the Organisers:

## HAMM&WITTKOPP

Patentanwälte



#### **HAMM & WITTKOPP**

A German based IP Law firm, as a team of chemists and biochemists with many years of experience, Hamm & Wittkopp represents its clients in all areas of intellectual property. A major focus of our activities lies in the fields of chemistry and pharmaceutics with particular emphasis on generic pharmaceuticals and biosimilars. We offer a comprehensive service of the highest level, from analyzing and clarifying the IP situation, for example via oppositions and nullity actions against troublesome patents, to securing your own innovations via patent applications and defending your interests in litigation proceedings. Our structure allows us to provide tailor-made support in all patent and trademark matters, whereby we are able to act flexibly and efficiently, whilst adapting to the specific needs of each individual case.

#### **CARLSON & CASPERS**

Carlson & Caspers is known for its excellence in intellectual property litigation and counseling. Founded in 2003 and based in Minneapolis, the attorneys serve sophisticated clients from individuals to Fortune 500 companies. In addition to substantial experience with all types of legal IP issues, the firm's attorneys bring industry knowledge and a real-world business perspective to courtroom challenges. The firm's partners and associates include a diverse team of technologists, scientists, engineers, chemists, pharmacists with outstanding support staff. The firm's high rankings include recognition by the American College of Trial Lawyers, Chambers USA, IAM Patent 1000, IP Stars, Best Lawyers, Super Lawyers, and others. Carlson Caspers consistently helps clients achieve positive business results through the protection and enforcement of their intellectual property.



## Gary J Speier

Gary is a registered U.S. patent attorney with a focus on issues facing companies in the life sciences sectors. He is a patent litigator who provides counsel on a broad range of patent-related matters and regularly conducts pre-suit investigations, intellectual property valuations and IP due diligence. Gary provides freedom-to-operate clearance reviews and opinions relating to infringement and validity, and develops patent procurement and patent prosecution strategies for domestic, international, and foreign jurisdictions. He has been involved in numerous post-grant proceedings (e.g., ex parte reexaminations and inter partes reviews) in front of the U.S. Patent and Trademark Office (USPTO). The post-grant proceedings have involved patents across diverse technology areas (e.g., medical devices, drug delivery systems, polymers, pharmaceuticals, new chemical entities, and process manufacturing).



## Peter Kohlhepp

Peter Kohlhepp practices intellectual property law focusing on high-stakes patent litigation and post-grant proceedings. His work spans a variety of technologies, including medical devices, automotive technology, pharmaceuticals and nutraceuticals, medical diagnostics, telecommunications, and energy. Peter has extensive experience representing clients before the US Patent Trial and Appeal Board (USPTO), including frequently delivering successful oral arguments before Board panels.



## Jennell Bilek

Jennell advises clients on a wide range of intellectual property and legal matters. She is a strong advocate for clients in and out of court. She takes pride in developing a deep understanding of the disputed technology and the business needs of her clients to achieve favorable outcomes. For instance, in a notable win from the District of Delaware, the Judge found six patents invalid for indefiniteness after the Markman hearing, which saved the client the expense of trial for six of the seven patents-in-suit. With strong briefs and argument, the decision was affirmed at Forest Labs., Inc. v. Teva Pharms. USA, Inc., 716 Fed. Appx. 987 (Fed. Cir. 2017). She represents plaintiffs and defendants in a variety of industries with experience in many forums such as Delaware, Minnesota, New Jersey, Southern District of New York, Connecticut, and the USPTO.





## Dr. Alexander Wittkopp

Alexander is a partner at Hamm & Wittkopp Patent Attorneys, based in Hamburg (Germany). He represents his international clients in the areas of German, European, and US intellectual property law, including patent prosecution, oppositions, nullity and infringement proceedings, as well as preparing freedom-to-operate and validity opinions in the field of 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. He regularly provides complete FTO-analyses for generic products and biosimilars, conducts detailed assessments of the relevance and validity of crucial proprietary rights, and represents his clients in oppositions and revocation actions.



### Dr. Nils Kahlcke

Nils is an Associate at Hamm&Wittkopp Patent Attorneys, based in Hamburg (Germany). He represents national and international clients before the EPO and the UPC patent with a focus on oppositions, appeals as well as nullity and infringement proceedings in the field of organic chemistry and pharmaceuticals. Nils is a qualified German and European Patent Attorney, as well as a European Patent Litigator. He regularly provides complete FTO-analyses for generic products, conducts detailed assessments of the relevance and validity of crucial proprietary rights.



### Tarun Khurana

Tarun has over 20 years of experience in a broad range of Intellectual Property (IP) subject matters, and is the Co-Founding Partner and Patent Attorney of Khurana & Khurana (K&K) and of its Patent Research and IP Asset Management Firm, IIPRD, both of which are among the Leading IP and Commercial Law Practices with 10 Offices in India, and over 220 Professionals. The firms also have regional offices in US, GCC/UAE, Thailand, Indonesia, Vietnam, Myanmar, Bangladesh, Malaysia, Sri Lanka, and Nepal. Tarun is ranked among the top Patent Prosecution Practitioners in India by IAM 1000 (and also by IAM 300 Strategists), and focuses on Patent Portfolio Management, Litigation, Valuation and IP Commercialization mandates for numerous Indian and International Corporates ranging from Small Start-ups to Fortune 5 companies.



## Tapan Shah

With more than 12 years of experience in providing specialized services in Patents and related Intellectual Property Rights, Tapan holds expertise in the technical domains of Organic Chemistry, Medicinal Chemistry, Pharmaceuticals, Biotechnological products and Medical Devices. He holds Master's Degree with specialization in Medicinal Chemistry from National Institute of Pharmaceutical Education and Research (NIPER, Mohali) Tapan has diverse experience in devising and assisting Fortune 500 Pharmaceutical and Chemical companies, US and European Law firms, independent patent attorneys and In-house patent counsels towards development and commercialization of products and processes.



# Registration Details:

#### **Delegate Fee Submission Details:**

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

- Full Name
- Organization
- Designation
- Complete Address
- Contact Number & Email ID

#### **Payment Instructions:**

Please make the delegate fee payment through bank transfer/ UPI using the following details:

Bank Account Details:

Account Holder Name: IIPRD
Bank Name: Axis Bank Ltd

Account Number: 917020069762436

Branch: Alpha Commercial, Greater Noida

IFSC Code: UTIB0000624 Account Type: Current



### For Any Queries, Please Contact:

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