

IN ASSOCIATION WITH

**KHURANA & KHURANA**  
**ADVOCATES & IP ATTORNEYS, INDIA****SUGHRUE MION, PLLC, USA****TEE & HOWE IP ATTORNEYS, CHINA****MAIWALD, GERMANY**

## Presents

### Three - Days International Symposium On

**Strategies For Managing Pharmaceutical,  
Biotechnology and Chemical Patent Portfolios  
(United States, European, And Chinese Scenario)**

**For  
R & D Scientists & IP Professionals  
With Focus  
On**

**5-7th October 2015  
at Hotel Hyatt, Vastrapur, Ahmedabad**

**7-9th October 2015  
at Hotel Hilton (Andheri East), Mumbai**



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# ABOUT THE SYMPOSIUM

With Patents becoming a core part of existing economic ecosystem, particularly for Pharmaceutical, Biotechnology, Chemical, and Drug Industries, exploitation of Patent Portfolio has become an industry in itself especially with the cost of development and protection of the portfolio being enormous. It is therefore crucial to understand important Patent issues, not only for IP teams but even more importantly for R&D Scientists so as to minimize efforts in Patent Development and maximize commercial gains. It is also important for Corporates and concerned stakeholders to understand nitty-gritty's of Patent portfolio creation, protection, management, and commercialization, without which there would always remain an open door for a serious blow either from an infringement perspective or from a patent invalidation perspective or the portfolio would remain under commercialized. This is precisely why the number of major patent litigations are growing between competitors and contemporaries, besides the growing threat from international exploiters.

Exclusivity rights granted through patents can only be utilised if there is comprehensive knowledge of various patent related issues, more so when the National Patent Laws & Practices relating to prosecution practices, drafting practices, examination practices, enforcement practices and commercialization practices differ substantially across geographies. Furthermore, standards for protection and enforcement as applied by different National judiciaries often vary widely and therefore in global business scenario, besides understanding of Patent Laws and Practices prevalent in India, we also need to understand practices in economically and financially important geographies such as in United States, Europe, and China. It is in this direction that the three days International Symposium is being organized to impart comprehensive knowledge to understand nitty-gritty of Patent Regime. The Symposium will provide an opportunity to receive first-hand information including recent Judgments on various issues from experts in the field.

## WHY THE DELEGATES SHOULD ATTEND

This is an opportunity when Patent Experts, Litigators and Legal Counsels from varied backgrounds and having enormous expertise and different perception would be interacting with limited delegates, and would answer to any question that the delegates may have. The speakers have thorough knowledge on the subject and have been working in the field for many decades. The speakers would share real-life cases and experiences that can help attendees in following best practices for building their respective patent portfolios so as to best commercialize.

## WHO SHOULD ATTEND

IP Management Teams, Research & Development Scientists, Patent Agents & Attorneys in the field of Practice, Patent Litigators, Professionals in Legal-Business domain related to Pharma, Biotech and Chemical Industry.

## SCHEDULE

### Dates & Venue:

- (i) 5-7th October 2015, at Hotel Hyatt, Vastrapur, Ahmedabad
- (ii) 7-9th October 2015, at Hotel Hilton, (Andheri East) Mumbai

## REGISTRATION FEES:

Rs. 12000/-Per delegate (If 3 or more delegates are nominated by any company, the delegate fees will be Rs. 10000/- Per delegate). For Foreign Delegates: USD 300 Per Delegate.

Please forward the Delegate Fees with following details: Name, Organization, Designation, Address and Contact Details along with the cheque drawn in favour of "M/S IIPRD" to Mr. Tarun Khurana

IIPRD

E-13, UPSIDC Site-IV, Kasna Road, Greater Noida-201308, UP, India.

OR

Transfer Funds at our Bank; details are as Follows:

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For any query, contact:

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- (ii) Mr. Tarun Khurana, (M) 9810617992, E-mail:- Tarun@iiprd.com, iiprd@iiprd.com  
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# PROGRAMME - DAY - 1 [US Scenario]

Registration: 0900 hrs onwards

Session-I

0930-1100 : Possible new grounds of Paragraph IV invalidity challenges: How 101 rejections under *Myriad* and findings of 112 indefiniteness under *Nautilus* may alter Paragraph IV Litigation; How 101 prosecution rejections may translate to 101 invalidity challenges of a small molecule drug in a Paragraph IV setting at the District Court level; Analyzing *CLS Bank v. Alice Corp.* and its relationship to *Myriad* relative to 101;

1100-1115 : Tea Break

Session-II

1115-1215 : Study of new obviousness criteria for Paragraph IV compound patent challenges post-KSR and in light of *Bristol-Myers Squibb Company v. Teva Pharmaceuticals USA (BMS v. Teva)*: Analyzing the criteria for lead compound analysis and understanding how *BMS v. Teva* will impact both prosecution and litigation under Hatch-waxman

Session-III

1215-1315 : Analysis regarding the impact of Supreme Court decision *Teva v. Sandoz* on patent litigation; discussion on standard of review for claim Construction: De Novo vs. Deferential; Review of other Key Supreme Court Cases that May Alter the Course of Paragraph IV Litigation

1315-1415 : Networking Lunch

Session-IV

1415-1545 : New USPTO interim guidance on patent subject matter eligibility: Best practices for applying the new guidelines in application drafting and prosecution; How will examiners apply the new guidance?; Insight into how the Interim Eligibility Guidance may impact strategies involving owned or in-licensed intellectual property

1545-1600 : Tea Break

Session-V

1600-1730 : Advanced Strategies for Pleading and Effectively Using Motions Practice in Paragraph IV Disputes; New Exclusivity Challenges for Brand Names and Generic and Related Implications for Paragraph IV Challenge

# PROGRAMME - DAY - 2 [US Scenario]

Session-VI

0915-1015 : Evaluating the risk and commercial opportunity in the emerging US Biosimilars space; Meeting USFDA's standards for biosimilarity Incorporating *inter-partes* review into Branded and Biosimilar Litigation Strategies; Anticipating how the complex patent resolution provisions in the BPCIA will interplay with the patent validity proceedings at the USPTO;

Session-VII

1015-1115 : Understanding how BPCIA timelines play out in practice: How to prepare for "early" and "late" phase litigation: Designing around the timelines; Specific considerations for brand-vs-brand and generic-vs-generic; A review of the BPCIA cases *Sandoz v. Amgen* and *Celltrion v. Janssen*

1115-1130 : Tea Break

Session-VIII

1130-1300 : How monumental changes under the AIA including inter parties review (IPR) and post-grant review (PGR) should influence Paragraph IV litigation strategies; Assessing strategic benefits that can be derived from IPR as opposed to district court litigation; how the different burdens of proof in obviousness challenges before the federal courts and PTO may impact litigation strategies;

1300-1400 : Networking Lunch

Session-IX

1400-1500 : Post-Grant Patent Challenges at the PTAB: Proven strategies for asserting or defending a patent challenge at the PTAB - avoiding common procedural pitfalls and effective litigation tips for obtaining successful results; parallel patent proceedings before the PTAB and federal court post-AIA; What challenges are being faced when challenging or defending patent validity in concurrent proceedings?

Session-X

1500-1600 : Best Practices to Secure Patent Allowance using Evidence: Evidentiary declarations under the First to File system including declarations relating to the 1-year grace period under the new section 102(b); How Rule 132 declarations and other evidence are explained to overcome obviousness rejections; How to avoid common pitfalls that can sink a patent during litigation;

1600-1615 : Tea Break

Session-XI

1615-1700 : How do AIA changes impact the on sale bar and the public use bar? How are courts treating the on sale bar and the public use bar? What best practices can be employed to adapt patent prosecution and enforcement strategies?

1700 onwards: Prize Distribution for National Patent Drafting Competition (NPDC)

# PROGRAMME - DAY - 3 [EP & Chinese Scenario]

0930-1030 :

## Session-I

- Best practices to prosecute pharmaceutical/chemical/biotech related patent applications in China
- Obviousness - what arguments would help you through a Chinese Examiner more easily?
- Non-patentable subject matter - what are subject matters that will not be allowed?
- Support - importance of including experimental data in your Patent Specification
- Sufficiency - particularly related to testing methods
- Understanding requirements for obtaining a valid patent

1030-1045 : Tea Break

## Session-II

1045-1200 :

- Freedom-to-operate searches and opinions in China
- Overcoming the challenge of obtaining reliable search data
- How do FTO processes and procedures in China differ?
- IP trends and regulatory changes in China that can shape your FTO strategies
- Protecting your patents from infringement in China
- How are Chinese Courts dealing with infringements?
- Take away message

## Session-III

1200-1330 : Recent decisions in pharmaceutical patent law of the EPO, the ECJ, and the national patent courts in Europe; Consequences for the drafting and filing of generic patents, for the validity of patents and supplementary protection certificates, and for the handling and marketing of generic products

1330-1430 : Networking Lunch

## Session-IV

1430-1530 : Update on the implementation of the Unified Patent System and the Unified Patent Court

1530-1545 : Tea Break

## Session-V

1545-1700 : IP Portfolio management, Assignment, Infringement Issues in India, Importance of Due Diligence in Managing IP Portfolio, and Understanding Methodology of IP Valuation.

## ABOUT THE FACULTY



**Mr. Chid Iyer:** Chid received a B. Tech in Chemical Engineering from IIT, Bombay in 1984, MS in Chemical Engineering from University of Akron and MS in Computer Science from the University of Tennessee Space Institute. He received his JD from Georgetown University in 1997. Chid is a partner of International Law Firm of Sughrue Mion and is involved in all aspects of patent practice including litigation, prosecution and client counselling in a variety of technologies with focus on chemical and pharmaceutical. Chid has prepared and prosecuted over 100 applications for a leading research laboratory.



**Mr. Michael R. Dzwonczyk:** Michael is a partner at Sughrue Mion and has about 20 years of experience in successfully representing multinational companies in patent litigation, including trials and appeals of patent cases. His experience has encompassed technical areas that include pharmaceuticals, recombinantly produced hormones, protein synthesis and expression products, fibers, and medical devices. Michael also counsels clients on intellectual property issues, including validity and infringement of intellectual property rights, licensing and contract matters and Hatch-Waxman issues.



**Ms. Aiyda Ghahramani:** Ms. Aiyda practices in all areas of intellectual property law with a focus on litigation, rendering opinions on patentability, infringement, and validity, as well as on the prosecution of intellectual property matters. Aiyda is actively involved in connection with preparation of Paragraph IV Notifications under section 505(b), as well as freedom-to-operate, due-diligence and product clearance work, licensing and contract matters, including joint ventures.

# ABOUT THE FACULTY



**Mr. Shackelford:** Mr. Shackelford is an associate in the chemical patent and biotechnology / pharmaceutical practice groups, where he maintains an active patent prosecution and litigation practice. Prior to joining Sughrue Mion, Mr. Shackelford taught IP courses for LL.M. and J.D. students and conducted research into patent claim construction. During law school, Mr. Shackelford earned his J.D. from the IIT Chicago-Kent College of Law, where he was a member of the Moot Court Honor Society and Law Review. He received his B.S. in Biochemistry from the University of Missouri-Columbia and M.S. in Chemistry and Chemical Biology from the University of California, San Francisco.



**Ms. Azy S. Kokabi:** Azy S. Kokabi's practice focuses on worldwide procurement, defense and enforcement of patents in the biotechnology and pharmaceutical industries, with focus on prosecution, interference, and litigation motions practice. Kokabi did her post graduation in Biology and JD from George Mason University School of Law. Kokabi has served as counsel in interference proceedings and related matters, before the Board of Patent Appeals and Interferences and the Court of Appeals for the Federal Circuit. Prior to joining Sughrue Mion, Ms. Kokabi also served at the U.S. Patent and Trademark Office as an Examiner.



**Dr. Toby Mak:** Dr. Toby Mak is a registered Chinese Patent Attorney and has a PhD degree in Chemistry. Toby has over 10 years of experience in patents and designs. He has substantive experiences in handling both contentious and non-contentious matters, including prosecution, invalidation and enforcement. Dr. Mak, He has served many clients of different technical fields and has a strong focus on Pharma and Bio practice and has been closely associated with research institutes and universities. Dr. Mak is a member of the All-China Patent Agents Association, and a foreign member of the UK Chartered Institute of Patent Attorneys."



**Yeping DING:** Ms. Ding graduated from Sichuan University in 1989 with a BS degree in bio-engineering and obtained her M.S. in genetics from Chinese Academy of Sciences (CAS) in 1995. Ms. Ding was admitted to practice as a certified patent attorney in 1996. From 1995 to 2004, Ms Ding worked with China Sinda Intellectual Property Ltd as an assistant and patent attorney. Her 10-year practice in Chinese patent prosecution covers the technical areas of biology, pharmaceuticals, chemistry and chemical engineering.



**Dr. Alexander Wittkopp:** Alexander is a managing partner at Maiwald Patentanwälts GmbH, 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. His experience encompasses the synthesis and morphology of APIs, pharmaceutical compositions of generic drugs and biosimilars, medical devices, combinations of pharmaceutical agents, and 2<sup>nd</sup> medical uses. Alexander is a qualified German and European Patent Attorney, as well as a US Patent Agent. He practices regularly before the German and European Patent Office, the German District Courts, the German Patent Court, and the Federal Court of Justice.



**Mr. Vinod Khurana:** Vinod has been in the field of Legal-Finance, Investigation and Prosecution for the last 40 years. Vinod is the Founder Director of IIPRD ([www.iiprd.com](http://www.iiprd.com)). Vinod is also the Founder President of the Institute of Forensic Accounting and Investigative Audit ([www.ifaia.org](http://www.ifaia.org)). Vinod is also a Senior Partner legal 500 Khurana & Khurana Advocates & IP Attorneys ([www.khuranaandkhurana.com](http://www.khuranaandkhurana.com)) and Litigates Fraud/ Infringement/ Contractual-disputes related matters. Vinod has undertaken more than 150 National and International symposiums globally on fraud/ infringement issues and has investigated hundreds of frauds and infringement matters. Vinod is member of Delhi Bar Council.

# ABOUT THE ORGANIZERS

**IIPRD:** IIPRD is a premier IP Consulting and Licensing Firm with a diversified business practice providing services in the domain of Commercialization, Valuation, Licensing, Transfer of Technology and Due-Diligence of Intellectual Property Assets along with providing complete IP and Patent Analytics and Litigation Support Services to Indian and International Corporate and Global Law Houses. IIPRD has a legacy of over fifteen years of existence, and is among the first Indian IP Firms to have core focus on Commercialization, Technology Transfer, and Licensing for numerous Indian and Global Corporate.

**Sughrue Mion:** Sughrue Mion is one of the world's leading intellectual property law firms managing traditional and non-traditional intellectual property rights, for about five decades, with a wide range of clients around the world. Sughrue's Pharmaceuticals, Biotechnology, Chemical attorneys are trained in technical disciplines that include molecular and cellular biology, biophysics, pharmaceuticals, chemistry, immunology, virology, genetics and agriculture biotechnology. Their experts are particularly well versed in drafting claims to ensure the broadest possible coverage and have a long established expertise in handling patent interference proceedings that may be critical to determining basic patent rights in new areas of biotechnological and pharmaceutical industries. Sughrue Mion handles a wide range of IP litigation matters for clients around the world, and when it comes to serving their clients, they go beyond traditional boundaries, advocating innovative theories and redefining the frontiers of law as they apply to creativity and invention.

**Khurana & Khurana Advocates & IP Attorneys:** To most of our clients, Khurana & Khurana, Advocates and IP Attorneys (K&K) is more than a full service Intellectual Property and Commercial Law firm. K&K was formed with a very firm focus of providing End-to-End IP Legal Services in a manner that is Corporate centric and follows delivery practices that are consistent and are above defined quality standards so as to ensure "Above Expectations" for all clients. Khurana & Khurana is among the leading Indian IP and Commercial Law Firms with over 65 Associates and Practitioners across IP subject matters and spread across its offices in Delhi (Noida), Mumbai, Bangalore, and Pune. K&K has been consecutively ranked and recommended by premier magazines and organisations namely Managing IP, IAM, Legal 500, Asia IP, Chambers & Partners, Corp-INTL, Acquisition INTL, among many others. K&K has won the "IP Patents Law Firm of the Year in India" and "IP Valuation Firm of the Year" consecutively for the three years 2012-13, 2013-14, and 2014-15 by Corporate INTL and Acquisition INTL magazine respectively. K&K has been a member of various renowned IP bodies including, APAA, INTA, AIPPI, LES, TIE, ABLE etc.

**Tee & Howe IP Attorneys:** Tee & Howe is one of the leading Chinese IP Firm advising multinational clients since early 1990s. Tee & Howe's practice covers all aspects of patent and trademark law, encompassing all phases of pursuing, licensing, maintaining, and litigating patent and trademark rights. Tee & Howe is one of the patent firms licensed by Chinese government to represent foreign clients. The firm has 32 patent attorneys, one US patent attorney, 10 trademark attorneys, 6 attorneys at law and about 60 patent engineers and assistants. Most Tee & Howe attorneys have more than 10 years experience in advising and representing clients in patent prosecution, invalidation and infringement litigation. Tee & Howe has a strong practice in Pharmaceutical and Biotech domains.

**Maiwald Patentanwalts-gesellschaft mbH:** Maiwald is one of the largest IP firms in Germany representing clients in the prosecution and litigation of patents in all fields of intellectual property, including all procedures before the patent and trademark offices as well as litigation before the relevant courts through all appeal instances. Maiwald's patent attorneys and attorneys-at-law have long experience and expertise in protecting a wide variety of technical inventions.