THREE DAYS SYMPOSIUM ON
PHARMACEUTICAL, BIOTECHNOLOGY & CHEMICAL PATENT LAWS
FOR R&D SCIENTISTS & IP PROFESSIONALS

November 12 - 14, 2018
Hotel Taj Krishna, Hyderabad

November 13 - 15, 2018
Hotel Hilton, (Andheri East) Mumbai

ABOUT THE SYMPOSIUM:

With Patents becoming a core part of existing economic ecosystem, particularly for Pharmaceutical, Biotechnology, Chemical, and Drug Industries, creation and 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 Corporate and concerned stakeholders to understand nitty-gritties of Patent portfolio creation, promotion, 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 utilized 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-gritties of Patent Regime.

HOW THE SYMPOSIUM IS UNIQUE:

This Symposium features presentation of all important patent issues as mentioned in this brochure. The speakers are a unique gathering of Patent Attorneys, Litigators and Legal Counsels who have extensive years of experience in their professional fields and are well acquainted with the Industry's need. These speakers will put across to the delegates the real insight of Patent Laws, Practices and Commercial perspectives as prevalent and practiced in United States, Europe, India, and China. The Workshop will provide an opportunity to receive first- hand information including recent Judgment on various issues from the experts in the fields. The speakers are selected such that R&D Scientists, In- House Counsels, Patent Attorneys, and IP Practitioners can get to know real insights and nitty- gritties followed in the United States, Europe, India and China in Patent Domain. 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.

Organizers:

KHURANA & KHURANA
ADVOCATES AND IP ATTORNEYS

Sughrue
SUGHRUE MION, PLLC
INTELLECTUAL PROPERTY LAW

LEXGOAL
IP LAW OFFICE

IIPRD

HAMM & WITTKOPP
Patentanwälte

WHO SHOULD ATTEND:

In-house Counsels, Life Science Companies, 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.

REGISTRATION FEES:

Indian Delegates:

INR 15,000 Per Delegate

Foreign Delegates:

USD 300 Per Delegate

Schedule

Date	Hyderabad	Mumbai
12/11	US Practices-Part 1	
13/11	US Practices-Part 2	EP/China/India Practices
14/11	EP/China/India Practices	US Practices-Part 1
15/11		US Practices-Part 2

KHURANA & KHURANA ADVOCATES AND IP ATTORNEYS

NOIDA (NCR) | DELHI | PUNE | MUMBAI | BANGALORE | HYDERABAD | INDORE
US | VIETNAM | MYANMAR | BANGLADESH | NEPAL | MALAYSIA

IIPRO

Sughrue SUGHRUE MION, PLLC INTELLECTUAL PROPERTY LAW

We Are Delighted To Invite You For

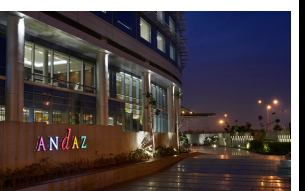
Sughrue Mion (U.S.) and Khurana & Khurana Pre APAA Reception

Friday, November 16, 2018

06:30 pm to 07:30 pm	|	Session on Work-Life Balance
07:30 pm to 10:00 pm	|	Cocktail Ceremony

Enlightening Session By A Well Known Indian Spiritual Guru on Managing Work-Life Balance and Inner Peace

RSVP
events@khuranaandkhurana.com



Andaz Delhi, Aerocity
New Delhi, India, 110037

We look forward to your presence

SESSION OUTLINE:

US Scenario:

09:00 AM TO 9:30 AM - REGISTRATION

09:30 AM TO 11:00 AM - Update on recent Fed. Cir. Pharma cases

An update on the past year's pharma cases at the Federal Circuit and Supreme Court provides needed guidance for Pharma companies making decisions and formulating legal positions about challenges and defenses to pharmaceutical patents.

11:00 AM TO 11:15 AM - TEA BREAK

11:15 AM TO 12:15 PM - Post-SAS implication on parties to the IPR and estoppels issues on future district court litigations

Scrutinizing SAS Institute Inc. v. Matal: The Supreme Court's issuing long-awaited decision, requiring the PTAB to address the patentability of every challenged claim in IPR petition; the PTAB cannot select a subset of the challenged claims and only rule on the subset. What will happen to instituted proceedings, especially those close to trial?

12:00 PM TO 01:15 PM - Patenting the label: the new standards for determining induced infringement based on statements in the product label

Far beyond the "Indications and Usage" section of product labels, patents routinely claim label sections directed to pharmacokinetics, bioavailability, metabolism, clinical results, black box warnings and more. Proof of induced infringement under §271(b) requires a showing of intent to achieve the claimed property or cause the claimed effect based on the language of the product label. Recent decisions in Sanofi, Eli Lilly and GlaxoSmithKline show the changing contours of induced infringement based on all parts of the product label.

01:15 PM TO 02:15 PM - NETWORKING LUNCH

02:15 PM TO 03:45 PM - What constitutes a Concrete Injury-in-Fact?

Determining what constitutes a 'Concrete Injury-in-Fact' through case of Momenta Pharmaceuticals Inc. v. Bristol-Myers Squibb Co.; Can a company show injury, which has not yet developed a product that infringes the patent?

03:45 PM TO 04:00 PM - TEA BREAK

04:00 PM TO 05:15 PM - Pitfalls and strategies to adopt in venue related issues in Hatch-Waxman litigations

Understanding how critical is the influence of venue in patent infringement through TC Heartland LLC v. Kraft Food Group Brands LLC where the SCOTUS held the State of incorporation for purposes of the patent venue statute; and in Bristol-Myers Squibb Co. v. Mylan Pharmaceuticals Inc., in which the SCOTUS under §1400(b) considered venue to be proper where a defendant has committed acts of infringement. Also discussed is the relevance of these cases to non-US companies and their prosecution strategies for Pharma patents

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SESSION OUTLINE:

09:15 AM TO 10:30 AM - Claim construction through Markman: what constitutes the active ingredient?

Assessing claim construction in Sumitomo Dainippon Pharma Co.et al. v. Emcure Pharmaceuticals et al., evaluating if the claim constructed in Markman ruling holding "lurasidone, lurasidone's enantiomer, as well as a mixtures of these enantiomers" as the active ingredient proper.

10:30 AM TO 11:30 AM - Obviousness post KSR in ANDA litigation & Can hindsight be avoided?

Taking clues from: Merck Sharp & Dohme Corp. v. Hospira, Inc., what evidences will make a strong case for obviousness post KSR in ANDA litigation despite evidence of commercial success and copying by others; Federal Circuit's finding in Merck Sharp & Dohme B.V. v. Warner Chilcott Co., when it is proper to avoid hindsight in considering whether a claim is obvious?

11:30 AM TO 11:45 AM - TEA BREAK

11:45 AM TO 01:00 PM - PTAB Update: Recent Challenges to Pharma patents, scorecards and trends to watch

Survey of recent pharmaceutical patent challenges, wins, and losses at the PTAB; analyzing trends by patent owners, patent challengers and the PTAB; how the Supreme Court's recent decision in SAS is affecting PTAB practice.

01:00 PM TO 02:00 PM - NETWORKING LUNCH

02:00 PM TO 03:00 PM - "Reasonable Expectation of Success' in Hatch-Waxman Obviousness & 'unclean hands doctrine'

Gaining insight from Genzyme Corp. v. Dr. Reddy's Labs., Ltd. wherein U.S. Federal Circuit clarifies to the patent challengers, how the 'Reasonable Expectation of Success' should be satisfied in Hatch-Waxman Obviousness when attempting to invalidate patent; and how prejudicial can be 'unclean hands doctrine' from Gilead Sciences, Inc. v. Merck & Co., wherein the Federal Circuit barred Merck from asserting two patents against Gilead.

03:00 PM TO 04:00 PM - Recent Applications of §101 in Challenges to Method-of-Use and other pharmaceutical patent claims

What are the recent trends in the use of §101 to challenge method of use and other pharmaceutical patent claims? What challenges have been successful and how can claims better be drafted to survive these challenges? An analysis of Vanda Pharmaceuticals, Inc. v. West- Ward Pharmaceuticals International, Ltd. illustrates the Federal Circuit's most recent statements about section 101 challenges in Hatch Waxman cases.

04:00 PM TO 04:15 PM - TEA BREAK

04:15 PM TO 05:15 PM - How not to invalidate your own patent, through acts during prosecution:

Determining what are the criteria of 'exceptional case' in Howmedica Osteonics Corp v. Zimmer Inc., wherein the U.S. District invalidated four patents that Howmedica claimed were infringed, in view of "selective disclosure of data and evasive responses" to a patent examiner during persecution and awarded $13M Fee to Zimmer.

Venue:

November 13 - 15, 2018
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SESSION OUTLINE:

EP Scenario - 09:15 AM TO 01:15 PM

What all reasonable steps companies should take to show no intent of infringement

A take home from the decision of the Dutch Supreme Court in *Novartis/Sun* litigation relating to Novartis' (second medical) use patent, what all reasonable steps companies should take to pass the test "*did everything in its power to prevent this use (infringement)*".

Problem Solution Approach, where do we go wrong?

Brussels court of commerce confirmed the three-in-one formulation patent of Orion invalid due to lack of inventive step applying the problem-solution approach, despite unexpected therapeutic efficacy; whereas Commercial Court number 5 of Barcelona, due to 'error in defining the technical problem to be solved' considered unnecessary to proceed further with analysis of obviousness by the problem-solution method. Important lessons for those drafting EP patent applications.

Being mindful about clinical trial and date of filing of patent application

Learning from the decision of the European Boards of Appeal revoking patent, construing patent for a second medical use to lack inventive step over the patient consent form of the clinical trial; a key teaching for ANDA litigators how to use clinical trial data to invalidate patents.

11:45 AM TO 12:00 PM - TEA BREAK

Exceptional verdicts of English Courts: Ramifications on novelty infringement relationship and "principle of general application" for determining sufficiency

Assessing the UK High Court judgment in *Generics (UK) Ltd v Yeda*, does this decision means that the novelty and infringement no longer go hand in hand? Can invention properly be described as a "principle of general application" meets sufficiency? Answer is in affirmative in the decision of Court of Appeal in *Regeneron* patents concerning 'transgenic mice that produce hybrid antibodies'.

01:15 PM TO 02:00 PM - NETWORKING LUNCH

Chinese Scenario - 02:00 PM TO 04:00 PM

Emerging Life Sciences Patent Practice and strategies for optimizing successful patent prosecution in China

Prosecution of pharmaceutical/chemical/biotech patent in China, Patentability Requirements; Grace Period; Patent Obligation Penalties; Impact of new law on future patent litigation, recent IP trends and regulatory changes in China. Amendments to the Patent Law and important changes.

04:00 PM TO 04:15 PM - TEA BREAK

Indian Scenario - 04:00 PM TO 05:15 PM

Latest update and approaches for prosecuting Life Science Patent applications in India

Recent Changes in Indian Patent Procedures and Practices, Key Pharmaceutical Prosecution and Litigation Cases, Take Aways and Recommended Practices.

NOMINATION FORM

Please Forward the Delegate Fees with the following details:

Name, Organization, Designation, Address and Contact Details along with the cheque to be drawn in favour of:

" M/S IIPRD" addressed to:
Ms. Meenakshi Khurana ,
IIPRD, E-13,
UPSIDC Site-IV,
Kasna Road,
Greater Noida-201308, UP, India

Or

Transfer Funds to our Bank; details are as Follow:
Name of the Account Holder: M/S IIPRD
Bank Name: UCO Bank Branch, Branch Name: Greater Noida
Bank Account Number: 19620210002476
Bank Address: G.N. Shopping Plaza, Plot No.-S-7/1, Site-IV, Kasna Road, Greater Noida
MICR Code: 110028055
IFSC Code: UCBA0001962

FOR ANY QUERY CONTACT:
Bhumika (IIPRD)
(M): +91-8920269831 (T): +91-120-4296878
E: bhumika@khuranaandkhurana.com

ABOUT 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, Transactional, and Litigation Support Services to Indian and International Corporates, Licensing Firms, and Global Law Firms. IIPRD has been established precisely to assist business houses in strategizing their growth by leveraging their IPR's through effective Creation, Promotion, Protection, and Commercialization of IP. 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. IIPRD as strong team of over 110 professionals focus in complete Patent Support and Technology Consulting Matters ranging from conducting all types of Patent Searches, Research and Analytics, Preparation/Prosecution Support,Landscape Analysis, and Claim Charts/ Infringement Analysis/ Litigation Support.

KHURANA & KHURANA ADVOCATES & IP ATTORNEYS:

Khurana & Khurana, Advocates and IP Attorneys (K&K) is more than a full service Intellectual Property and Commercial Law firm. K&K was formed in the year 2007 with a very firm focus of providing end-to-end IP Prosecution/ Litigation and Commercial Law services in a manner that is Corporate centric and follows stringent delivery practices that are consistent and are above defined quality standards. K&K works closely with its sister concern IIPRD, both of which supplement each other in order to provide end-to-end IP Legal and Commercialization/Licensing services to over 3000 Corporates. K&K is a team of over 110 professionals spread across 7 Offices in India, and has strong rankings from Legal 500, MIP, IAM, Chambers, Asia IP, among others.Our team of IP Attorneys/Practitioners, having high level of technical and legal competence, gives us the right competitive edge and positioning, as a law firm focused on creating immense IP value for our clients. K&K through its experienced and qualified team of Attorneys/ Practitioners, across Technology and Legal Domains, gives a rare synergy of legal opinion, out-of-box thinking for protection of ideas/IP's and entrepreneurial spirits to its client base.

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 more than 100 lawyers protect ideas- all ideas- and for the last 50 years have been helping their clients to develop, obtain, protect and leverage their intellectual property rights in technology areas ranging from a submicroscopic sequence of DNA to a vast constellation of satellites circling the globe. Sughrue's Pharmaceuticals, Biotechnology, Chemical attorneys are trained in technical discipline s 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 dustries. Their litigators who specialize in chemistry have tried cases relating to pharmaceuticals, biotechnology, industrial chemical processes, specialty chemicals, and nano technology.

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.

ABOUT FACULTY:

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.

Grant Shackelford

Grant is an associate in the chemi-cal 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.

Michael R. Dzwonczyk

Michael is a partner at Sughrue Mion and has about 21 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 pharma-ceuticals, recombinantly produced hormones, protein synthesis and expression products, fibers, and medical devices. Michael also counsels clients on intellectual prop- erty issues, including validity and infringement of intellectual property rights, licensing and contract matters and Hatch-Waxman issues.

Travis Ribar

Mr. Ribar practices in all areas of intellectual property law with a focus on rendering opinions on patentability, infringement, and validity, including due diligence and product clearance analysis, as well as on the litigation of intellectual property matters, including reexamination practice. A former Patent Examiner at the USPTO, he also counsels and assists clients in the procurement of both U.S. and foreign patents, which includes the preparation and prosecution of patent applications. Mr. Ribar specializes in the areas of photoresist formulations and applications, rubber compositions, plastics and adhesives, membranes, medical and drug delivery devices, display devices, semiconductor materials, food compositions, polymeric materials, and the chemical arts.

ABOUT FACULTY:

Mark Boland

Mr. Boland has successfully represented a variety of companies in the U.S., Asia and Europe as lead counsel in numerous patent litigations before federal district courts and the U.S. International Trade Commission. His experience includes jury trials, bench trials and appeals before the Federal Circuit. He has also successfully represented clients in patent interferences before the USPTO and district court § 146 interference appeals. Mr. Boland also regularly engages in patent infringement and validity opinion practice and counseling, freedom-to-operate, due diligence and product clearance work, licensing and contract matters including joint ventures and co-development situations, patent application preparation and prosecution, and counseling clients in devising global intellectual property strategies. Mr. Boland advises companies involved in a variety of technologies, particularly pharmaceutical, chemical and biologically-oriented technology, as well as the mechanical arts. Mr. Boland is a member of the firm's Management Committee.

Tarun Khurana

Tarun has over 16 years of experience in a broad range of IP subject matters, and is the Co-Founding Partner and Patent Attorney of Khurana & Khurana, which is among the Leading IP Practices in India with 7 Offices and over 110 Practitioners. Tarun is among the top 12 Patent Prosecution Practitioners in India as rated by IAM, and has executed numerous assignments related to exercises of Patent Portfolio Creation, Protection, Prosecution, Litigation, Valuation and Commercialization for Indian and International Corporates. Tarun focuses on the Patent Preparation, Prosecution Electronics, Patent Valuation, Commercialization, and Litigation opinions for Computer Implemented, and Mechanical subject matters.Tarun has a Bachelors in Computer Science Engineering, a Masters in Software Systems, Bachelors in Law, an MBA from IIM Lucknow, and is in pursuit of his PhD.

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, 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.

Bela Dang

Bella has engaged in drug R&D, drug registration and drug IP affairs China in many pharmaceutical companies such as Shanghai Pharma Tech's new drug research and development (WuXi AppTec Group) , and has owned extensive experiences in pharmaceutical research and development, domestic and imported drug registration in CFDA and she is good at patent applications, patent analysis, patent layout and mining, patent litigation, intellectual property due diligence and risk management, prosecution of pharmaceutical/chemical/biotech patents in China as well as analyzing the patentability requirements. Bella often attends the related IP training, through which she studies and collects the information and knowledge regarding the patent obligation penalties, impact of new law on future patent litigation, recent IP trends and regulatory changes in china and amendments to the patent law and important changes. Also, Bella has recently participated in the judicial interpretation training organized by Beijing Higher People's Court on the revision of Chinese patent law and the latest regulations on patent priority review.