THREE-DAYS ANNUAL PHARMA SYMPOSIUM ON

PREPARATION, PROSECUTION AND LITIGATION IN U.S., EUROPE, CHINA, AND INDIA

WITH FOCUS ON

PHARMACEUTICAL, BIOTECHNOLOGY & CHEMICAL PATENT LAWS

FOR R&D SCIENTISTS & IP PROFESSIONALS

DATE	HOTEL HILTON MUMBAI	HOTEL TAJ BANJARA HYDERABAD
18/11	US Practices-Part 1	
19/11	US Practices-Part 2	EP/China/India Practices
20/11	EP/China/India Practices	US Practices-Part 1
21/11		US Practices-Part 2

ORGANIZERS:

- KHURANA & KHURANA (INDIA)
- IIPRD (INDIA)
- SUGHRUE MION (US)
- HAMM & WITTKOPP (EP)

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 Judgments 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:

K&K KHURANA & KHURANA ADVOCATES AND IP ATTORNEYS

IIPRD

Sughrue SUGHRUE MION, PLLC INTELLECTUAL PROPERTY LAW

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

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SESSION OUTLINE:

US SCENARIO (PART 1)

09:00 AM TO 9:30 AM - REGISTRATION

09:30 AM TO 11:00 AM - 'On-Sale' Bar: Post-Helsinn implication on On-Sale Bar in pharmaceutical industry

Scrutinizing Helsinn Healthcare v. Teva Pharmaceuticals: The Leahy-Smith America Invents Act (AIA) bars a person from receiving a patent on an invention that was "in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." 35 U. S. C. §102(a)(1). Supreme Court of USA has held that a confidential sale of an invention to a third party may place the invention "on-sale" for the purpose of the America Invents Act.

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

11:15 AM TO 12:15 PM - PTAB update: Recent CAFC rulings on PTAB decisions in Hatch-Waxman litigation

What are the recent trends in the ruling of CAFC over the PTAB decisions of pharmaceutical patents? Discussion of different CAFC rulings, Mayne Pharma International Pty. Ltd. V. Merck Sharp & Dohme Corp., BTG International Limited v. Amneal Pharmaceuticals, LLC. and Salix pharmaceuticals v. Mylan Inc. Highlighting winning strategies for both patent owners and challengers; Lessons for patent prosecutors that emerge from PTAB and federal circuit decisions.

12:15 PM TO 01:15 PM - Raising the bar: US court of appeals of federal circuit raises the bar on written description requirement-Nuvo Pharmaceuticals, In. v. Dr. Reddy's Laboratories Inc.

Reviewing the compliance of the written description requirement in chemical and pharmaceutical patents in line with the recent federal circuit decision, Nuvo Pharmaceuticals Inc v. Dr. Reddy's Laboratories Inc. Update on strategies for Hatch-Waxman litigation based on the enablement requirement by leveraging the recent ruling of different patent case laws.

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

02:15 PM TO 03:45 PM - Pitfalls and strategies to adopt in venue related issues in Hatch-Waxman litigations

Understanding the influence of venue in patent infringement through Novartis Pharmaceuticals Corp. v. Accord Healthcare Inc., et al., where the United States District Court for the District of Delaware determined that the patent-specific venue statute, 28 U.S.C. § 1400(b), not the general venue statute, 28 U.S.C. § 1391, applies to Hatch-Waxman patent infringement cases. Discussing strategies and steps to determine the right venue for Hatch-Waxman patent infringement cases.

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

04:00 PM TO 05:15 PM - Sequential order of process steps in claims limits the scope of infringement: Amgen Inc. v. Sandoz Inc.

Discussing the ruling of the US Court of Appeals for the Federal Circuit in Amgen Inc. v. Sandoz Inc. case illustrating how critical is the order of maintaining process steps in patent infringement.Scrutinizing best practices and advice for patent practitioners regarding claim construction when drafting patent applications or giving patent infringement opinions.

US SCENARIO (PART 2)

09:15 AM TO 10:30 AM - 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 Natural Alternatives International, Inc. v. Creative Compounds, LLC and Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, illustrate the Federal Circuit's most recent statements about section 101 challenges in Hatch Waxman cases.

10:30 AM TO 11:30 AM - PDiscovery disputes with special focus on bio-similar patent litigation: AbbVie v. Boehringer Ingelheim (D. Del)

Discussing the discovery disputes of reference product sponsors (RPSs) seeking manufacturing information from biosimilar manufacturers and biosimilar manufacturers seeking discovery from RPSs and even third parties. Highlights of how discovery related to manufacturing has become central to many BPCIA disputes.

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

11:45 AM TO 01:00 PM - Restriction requirement and prosecution estoppel in Hatch-Waxman litigation: UCB, Inc. v. Watson Laboratories Inc

Understanding the legal requirement of restriction requirement and whether the restriction requirement triggers prosecution history estoppel that limits the scope of an applicant's issued claim in view of federal circuit decision, UCB, Inc. v. Watson Laboratories Inc. Reviewing the consequences of restriction requirement considering the recent Hatch-Waxman cases.

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

02:00 PM TO 03:30 PM - PTAB update and strategies: New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings Under the AIA Before the PTAB

Gaining insights of the recent changes in PTAB practices and procedures with respect to new pilot program introduced by USPTO. Discussing the pros and cons of the new pilot program based on patent owners and petitioners perspective. Strategies for effectively using the new pilot program by patent owner and petitioners.

03:30 PM TO 03:45 PM - TEA BREAK

03:45 PM TO 05:00 PM - Impact of USPTO's revised Subject Matter Eligibility Guidance on pharmaceutical inventions

Understanding USPTO's revised Subject Matter Eligibility Guidance and its impact on determining the patent eligible subject matter of pharmaceutical inventions. Discussion on Alice/Mayo tests to adopt effective strategies of the patent eligible subject matters in patent litigation.

EP/CHINESE/INDIAN SCENARIOS

EP SCENARIO

09:15 AM TO 11:45 PM

Supplementary Protection Certificates (SPCs)

i) Recent decisions and recent referrals of the national courts and the European Court of Justice.

ii) Possibilities and risks resulting from the SPC export and stockpiling waiver.

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

12:00 PM TO 01:15 PM

Second Medical Use Patents

i) The validity of crucial patents in view of the EPO's plausibility criterium.

ii) Their literal scope and risks of direct infringement.

iii) The requirements to prevent an indirect/contributory infringement

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

02:00 PM TO 04:00 PM - CHINESE SCENARIO - 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

04:15 PM TO 05:15 PM - INDIAN SCENARIO - 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.

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 150 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 3500 Corporates. K&K is a team of over 160 professionals spread across 10 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 ange 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.

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 FACULTY:

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.

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.

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.

Michael R. Dzwonczyk

Michael is a partner at Sughrue Mion and has about 22 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 property issues, including validity and infringement of intellectual property rights, licensing and contract matters and Hatch-Waxman issues.

ABOUT FACULTY:

Tarun Khurana

Tarun has over 17 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 10 Offices and over 150 Practitioners. Tarun is among the top 10 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.

Chinese Speaker (To be confirmed)