



INSTITUTE OF INTELLECTUAL PROPERTY RESEARCH & DEVELOPMENT (IIPRD)

With Support of

SUGHRUE MION, PLLC, USA

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KHURANA & KHURANA,
ADVOCATES & IP ATTORNEYS

Presents

TWO-DAY

INTERNATIONAL
SYMPOSIUM

On

Strategies for Managing

Pharmaceutical,

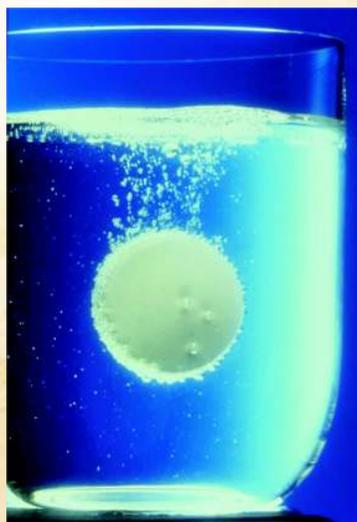
Biotechnology

&

Chemical Patent

Portfolios

With Focus On:



Strategies for Generics as Innovators, Biosimilar Legislation,
Latest Pharmaceutical Prosecution Practices & ANDA Litigation
On

10th-11th October 2011, at Hotel Hilton, (Andheri East) Mumbai

ABOUT THE SYMPOSIUM

With Patents becoming a core part of existing economic ecosystem, 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 patent holders but also for entities under the threat of potential patent infringement. With significant investment required for building a strong and enforceable patent portfolio, it is important for Corporates and concerned stakeholders to understand the 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. Furthermore, US Patent scenario provides great opportunity for Indian Pharmaceutical companies for ANDA litigation, nitty-gritty of which needs to be clearly understood. At the same time we need to understand that patents are not only the dictate of large business establishments but can also provide a great lead to small and medium business establishments which have given the whole business a new paradigm.

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, and enforcement practices differ substantially across geographies particularly for Pharmaceutical and Biotechnology domain. Furthermore, standards for protection and enforcement as applied by different National judiciaries often vary widely and therefore in the global business scenario, besides understanding of Patent Laws and Practices prevalent in India we also need to understand the practices in economically and financially important geographies such as United States. It is in this direction that the International Symposium is being organized to impart comprehensive knowledge to understand the nitty-gritty of Patent Regime related to Pharmaceutical, Biotechnology and Chemical domains for exploitation of exclusivity rights granted through patents to the best advantage of the Indian corporates.

HOW THE SYMPOSIUM IS UNIQUE

This Symposium features presentation of all important patent issues such as identification of potential inventions, Biosimilar Legislation, preparation of claim sets, prosecution and examination practices, drafting of responses of Office Actions, ANDA Litigation, and recent case law updates. The speakers are a unique gathering of Patent Attorneys, who have extensive years of experience in their professional fields, and will put across to the delegates the real insight of Patent Laws and Practices as prevalent and practiced in United States, in most coordinated manner as all speakers come from the same IP Law Firm. The Symposium will provide an opportunity to receive first-hand information including recent Judgment on various issues from the experts in the fields.

WHY ATTEND

This is a one time opportunity when Patent Experts from Sughrue Mion having varied backgrounds and enormous expertise 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 are selected such that the attendees can get to know the real insight and nitty-gritty followed at United States. The speakers would share real-life cases and experiences that can help the attendees in following the best practices for building their respective patent portfolios and how best to undertake ANDA Litigations. The speakers would also talk at length on the recent case laws and how courts of different geographies interpret the same application in different ways so that best practices for each geography can be put across. Sharing of practical experience would also help the delegates in gauging their understanding of complex patent issues and how claim construction can be interpreted for infringement or invalidation. Delegates would also get ample opportunities to interact with the speakers on confidential mode to understand and clarify any doubts and questions that they may have on personal basis. The knowledge gained from the workshop will go a long way in formulating the right patent strategy and building a strong and enforceable Patent Portfolio.

PROGRAMME OUTLINE

DAY 1

- 0900-0930 : Registration
- 0930-1115 : How recent biosimilars legislation is changing industry dynamics in the Hatch-Waxman landscape:
- Understanding the FDA's current position on the implementation of a biosimilar pathway
 - Determining what level of clinical data biosimilar applicants must provide to prove safety and efficacy
 - Debating the practical implications of a 12-year exclusivity period: Striking a balance between innovator and biosimilar interests
- 1130-1300 : How to Structure a patent portfolio strategy to protect IP in light of biosimilar legislation and how to develop proactive strategies and plans in preparation for the eventuality of biosimilar patent disputes
- 1300-1345 : Lunch
- 1345-1515 : Pre-suit due diligence strategies in anticipation of the paragraph IV challenge; Orange Book listings, delistings and related challenges; Resolving ANDA litigation: Settlement strategies; early market access agreements; authorized generics; FTC review; shared and unshared exclusivity, forfeiture, and citizens petitions.
- 1530-1645 : Recent Decisions Impacting Paragraph IV Challenges; declaratory judgment jurisdiction; an insight into on Teva Pharmaceuticals USA, Inc. v. Eisai Co., Ltd. (Fed. Cir. 2010);
- 1700-1830 : Bioequivalence and the "same active ingredient" vis-a-vis patentability; patenting of bioequivalence characteristics; extended-release drug products; bioequivalence v. Doctrine of Equivalents; arguments about bioequivalence raised in Paragraph IV patent litigation; infringement; Recent opinion on Cephalon infringement suit against Mylan, Barr et al.
- 1900 : Cocktail and Dinner

DAY-2

- 0915-1115 : Strategies for drafting patent applications in the pharma/chemical/biotech arts; Freedom-to-operate strategies and pitfalls in the chemical arts; unique perspectives on litigating pharma patents and litigation tips for drafting pharma/biotech applications;
- 1130-1315 : Explication of the contours of obviousness for pharmaceutical formulations after KSR v. Teleflex: In re Kao (Fed. Cir. 2011); Important post-KSR case law that chemical prosecutors in pharmaceutical arts need to know
- 1315-1400 : Lunch
- 1400-1600 : Current issues relating to reexamination; Accelerated Examination Practice; Prosecution strategies to overcome inherency rejections; Patent reform and the pharmaceutical industry: anticipating and adapting to change and salient features of the likely landmark legislation involving patent law in the US.
- 1615-1730 : Recent Case Law Update: Standards for establishing the inequitable conduct defense in Therasense, Inc. V. Becton, Dickinson & Co. (Fed. Cir. 2011); Failure to disclose material information v. false information.

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 counseling in a variety of technologies with focus on chemical and pharmaceutical. Chid has prepared and prosecuted over 100 applications for a leading research laboratory. Chid has conducted and presented in various workshops and seminars on patent practice at various locations in U.S, Korea, Japan, and India. He is currently chairing the AIPLA subcommittee on IP practice in India.



Mr. Kenneth J. Burchfiel: Burchfiel is a senior partner with Sughrue Mion. Burchfiel has expertise of 33 years in patent domain with focuses on Pharma, General Organic Chemistry and Biotechnology. Burchfiel was the first American patent lawyer admitted to practice in Japan under the reciprocal foreign law practice statute. His practice includes litigation before the federal courts, interferences and appeals. He also testifies as an expert witness on patent law and US PTO practice and procedure. In addition to his litigation and interference practice, Burchfiel counsels a variety of international and domestic clients regarding U.S. intellectual property law including providing clearance, enforceability, and validity opinions. Burchfiel has numerous publications and teaching and has spoken on various international symposium. He is also a visiting Scholar to Max-Planck among other universities/ Institutes.



Mr. Michael R. Dzwonczyk : Michael has over 17 years experience 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. His interference practice has included topics in chemistry and biotechnology including hormone and gene therapeutics, as well as anticholesterics. Michael also counsels clients on intellectual property issues, including validity and infringement of intellectual property rights, licensing and contract matters and Hatch-Waxman issues. He has lectured on topics including strategies for drafting pre-litigation opinions, pharmaceutical litigation strategies, and Patent Law Reform.



Dr. William Simmons : Simmons is an associate at Sughrue Mion and works out of the Washington office. He did his masters in Biological Sciences in 1995. Simmons practice focuses on worldwide procurement, defense and enforcement of patents in the biotechnology and chemical industries. Simmons works in all areas of patent law, including interferences, reexaminations, oppositions and prosecution. Simmons prepares opinions regarding patentability and infringement and conducts FTO analysis. He did his Post-doctoral Fellow from National Institute of Health at New York University.



Ms. Azy S. Kokabi : Azy S. Kokabi 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. Kokabi counsels clients about pre-interference matters, such as provoking or avoiding interference proceedings, copying claims, and evaluating inventorship disputes. Kokabi also prosecuted patent applications covering biotechnology subject matter, and assisting in the drafting of license agreements relating to intellectual property. She also assisted in various aspects of litigation, including researching and preparing legal memoranda for pharmaceutical and biotechnology litigations. Prior to joining Sughrue Mion, Ms. Kokabi also served at the U.S. Patent and Trademark Office as an Examiner.



SCHEDULE

Date : 10th-11th Oct' 2011

Venue : Hotel Hilton Mumbai (Andheri East)
(Earlier Known as Le Royal Meridian)

Fees : Rs. 13236/- Per Delegate (Rs. 12000/- + ST 1236/-)
Foreign Delegates - US\$ 350 Per Delegate

Service Tax Number : AABF16363FST001

NOMINATION FORM:

Delegate nomination form shall be sent to IIPRD duly completed with the following details: Name of the Corporate, Name of the delegate, Designation, Contact details of the delegate, along with the cheque drawn in favour of "Institute of Intellectual Property Research & Development" and mail it to IIPRD at:

Mr. Vinod Khurana

Institute of Intellectual Property Research & Development
IFAIA Centre, S/19-22, Greater Noida Shopping Plaza,
UPSIDC, Site-IV, Kasna Raod,
Greater Noida-201308, UP, India

FOR ANY QUERY CONTACT :

Contact Person : **Ms. P Suman** 0-9650843536 , E: iiprd@iiprd.com or
Ms. Meenakshi 0-9910307992, E: Meenakshi@iiprd.com
Ph : +91-120-2342010/3104849, Fax: 2342011

WHO SHOULD ATTEND

Research & Development Scientists, IP Managers, IP Professionals & Consultants, IP Agents & Attorneys in the field of practice, Business Risk Managers, Professionals in Legal Domain related to Pharmaceutical, Biotechnology & Chemical Industries

ABOUT THE ORGANIZERS

IIPRD

IIPRD is a premier Intellectual Property Consulting and Commercialization / 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 International Corporates and Global IP Law Firms. IIPRD also provides industrial training to Indian business houses. In this direction, IIPRD has been regularly holding International Seminars as one of its focused activities on its own and in collaboration with various Government and International agencies. IIPRD has held scores of National and International Programmes. IIPRD also conducts tailor made educational programmes for better known corporates at their premises specific to their needs. IIPRD has a legacy of over ten 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 Corporates, with Patent practitioners from across technology domains.

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 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. Their litigators who specialize in chemistry have tried cases relating to pharmaceuticals, biotechnology, industrial chemical processes, specialty chemicals, and nanotechnology.

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. In nut shell, Sughrue provides complete Intellectual Property development, protection, management and exploitation strategy, effectively, as single point Corporate destination in US and abroad. If you wish to know more about Sughrue Mion please log on to www.sughrue.com.

KHURANA & KHURANA, ADVOCATES & IP ATTORNEYS

Khurana & Khurana, Advocates and IP Attorneys is more than a full service IP Law firm. K&K was formed in the year 2006 with the very focus of providing End-to-End IP Legal Services along with IIPRD, which supplement each other in order to provide end-to-end services to the corporate world. K&K is among the youngest IP Firms to have been ranked and recommended by Legal 500 and represents numerous Fortune 500 Corporates for their IP Matters in India. K&K and IIPRD together form a niche in the IP domain by taking any corporate from the stage of IP Creation and Protection through its team of Attorneys to the stage of IP Valuation, Licensing, and Commercialization. The team of IP Attorneys /Practitioners having high level of technical and legal competence gives the right competitive edge and positioning to K&K as a law firm focused on creating immense IP value for its clients. K&K through its young and qualified team of Attorneys/Practitioners gives a rare synergy of legal opinion, out-of-box thinking for protection of ideas/IP's, and entrepreneurial spirits to its client base. K&K earnestly believes that success comes only when one has a long-term perspective and this is why K&K concentrates on building long-term relationships through high level of client orientation.