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With Support of

SUGHRUE MION, PLLC, USA
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KHURANA & KHURANA, ADVOCATES AND IP ATTORNEYS, India

Presents

THREE-DAYS

INTERNATIONAL

SYMPOSIUM

On

Strategies for Managing

Pharma, Biotech

&

Chemical Patent

Portfolio

With Focus On:

Patent Lifecycle Management, Strategies for Generics as Innovators, Biosimilar Legislation, FDA's Current Position & Patent Disputes, Latest Pharma Prosecution Practices & ANDA Litigation,

On

16th -18th September 2012, at Hotel Hilton, (Andheri East) Mumbai

ABOUT THE WORKSHOP

With the cost of Research & Development and protection of patent portfolio being enormous, exploitation of Patent Portfolio has become an industry in itself. 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 particularly in Pharma, Biotech & Chemical Industry. With significant investment required for building a strong and enforceable patent portfolio, it is important for IP team and all concerned stakeholders at corporate 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, patents are not only the dictate of large business establishments but can also provide a great lead to small and medium business establishments as well. At the same time, need for acquisition of Patents is also significantly expanding for large corporate; especially with the growth of international trade and globalization of economic activities, which have given the whole business a new paradigm. 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, and enforcement practices differ substantially across geographies. Furthermore, the standards for protection and enforcement as applied by different National judiciaries often vary widely, & 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 Europe and 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 Pharma, Biotech & Chemical domains for exploitation of exclusivity rights granted through patents to the best advantage of the Indian corporates.

HOW WORKSHOP IS UNIQUE & WHY THE DELEGATES SHOULD ATTEND

This Symposium features presentation of all important patent issues such as identification of potential inventions, types of claims allowed in each geography and their relevance to the broadness of claims, preparation of set of claims, prosecution and examination practices, drafting of responses of Office Actions, ANDA Litigation and issues related to biosimilars legislation and understanding the FDA's current position on the implementation of a biosimilar pathway. The speakers are a unique gathering of Patent Attorneys from USA & Europe 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 USA and European Patent Office. The Workshop will provide an opportunity to receive first-hand information including recent Judgment on various issues from the experts in the fields.

This is a one time opportunity when Patent Experts 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 are selected such that R&D Scientists, IP Managers, Patent Attorneys, and Legal Corporate Teams can get to know the real insight and nitty-gritty followed at European and United States Patent Offices. 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. 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. Delegates would have ample opportunities to discuss personal patent problems on a confidential basis with all or any of the speakers during the 3 days programme.

PROGRAMME

DAY 1 (EP SCENARIO)

0900 Onwards: Registration

0915-1100: Patent lifecycle management; Interplay between insufficiency of disclosure, inventive step and industrial applicability; Eli Lilly vs. HGS (EPO and UK)

1115-1300: Current trends in pharmaceutical and biotechnology patent law in Europe and recent case laws; when is a "kit" a "kit"? Second medical use claims (Carvedilol II, G2/08); Human stem cells (EPO and CJEU); Tomatoes and Broccoli (G1/08 and G 2/07)

1300-1345: Lunch

1345-1425: Getting your EP patent - Avoiding prosecution pitfalls at the EPO; Divisional applications; Added matter; Burden of proof in Examination

1430-1520: EPO Opposition and Appeal; Late filing; Art. 123(2)/(3) trap; Tips for Success

1535-1645: Patent extensions in Europe; Supplementary Protection Certificates (SPCs); New Decisions of CJEU in SPC matters; Paediatric SPC extensions

1655-1745: Enforcing your EP patent; Judicial systems; Doctrine of equivalence (FCJ Okklusionsvorrichtung, Diglycidverbindung)

DAY-2 (US SCENARIO)

0930-1030: New developments in U.S. regarding biosimilar pathways including scientific considerations in demonstrating biosimilarity draft guidance; Eligibility for filing and approval, as well as trade secret protection; Potential patent prosecution and litigation challenges related to use of the pathway.

1030-1215: How is the adequacy of written description and enablement determined? What must be done to meet the disclosure requirements after the *Ariad* decision? Strategies for successful disclosure of inventions in patent specifications in the U.S.

1215-1300: Strategies for efficiently obtaining patents; Strategies for handling a restriction or a lack of unity requirement; the use of interviews; expedited examination options; affidavit practice

1300-1345: Lunch

1345-1515: Which claims to be extended in patent term extension? Eligibility of patents for patent term adjustment; Orange Book listings; Rationale underlying a patentee's decision as to which patents to assert against patent challengers? Obstacles which can delay 180 day exclusivity period

1530-1630: Latest trends in Paragraph IV litigation? Which strategies have been successful? An update on recent Para-IV disputes & litigation in Court and at the Federal Circuit.

1630-1750: Strategies used for litigating different types of listed claims, such as claims to compounds, formulations, methods of treatment etc.; who are the infringers and how is infringement proven?

1800-1900: A brief discussion on Compulsory Licensing in India. Impact on generic industry and innovator industry and a road ahead?

1900 onwards: Cocktail and Dinner

DAY-3

0915-1115: Key provisions of the America Invents Act (AIA); a discussion of the widely expanded landscape of post-grant validity challenges, impact on patent valuation, enforcement and licensing.

1130-1315: New AIA provisions in the context of the Hatch Waxman regulatory scheme; Will they provide an earlier opportunity to challenge Orange book listed patents then those presently available? Strategic uses of AIA procedures in litigation management, licensing, and as an overall business strategy.

1315-1400: Lunch

1400-1445: A discussion of *Therasense* and the future of inequitable conduct, particularly in view of how courts have treated inequitable conduct issues post-*Therasense*.

1445-1600: Recent changes to the law of divided infringement; enforcement of method of treatment claims against ANDA applicants; applicability of claims for induced and contributory infringement

1615-1730: Status of patent eligibility in view of *Prometheus*, Review of patent eligibility from the perspective of the PTO & Courts; series of short topics of interest related to pharma practice.

SCHEDULE

Dates : 16-18th September 2012
Venue : Hotel Hilton (Andheri East) Mumbai
Registration Fees : Rs. 13000/- for Indian Delegates , USD 300 for Foreign Delegates

Please forward the Delegate Fees with the following details: Name, Organization, Designation, Address and Contact Details along with the cheque drawn in favour of "'M/S IIPRD" UCO Bank A/C Number 19620210002246" to IIPRD at :

Mr. Vinod Khurana
IIPRD, IFAIA Centre, S/19-22, Greater Noida Shopping Plaza,
UPSIDC Site-IV, Kasna Road,Greater Noida-201308, UP, India.

For any query contact: **Ms. Meenakshi Khurana,** (M)91-9910307992
E-mail:- meenakshi@iiprd.com, iiprd@iiprd.com
Ph: +91-120-2342010, Fax: +91-120-2342011

WHO SHOULD ATTEND

Research & Development Scientists, IP Managers, Patent Agents & Attorneys in the field of Practice, Patent Litigators and Managers in Generic Drug Companies, Professionals in Legal Domain related to Pharma, Biotech and Chemicals.

ABOUT THE FACULTY

Dr. Stephan Disser: Dr. Disser studied chemistry at the University of Frankfurt and received a scholarship from the Chemical Industry Trust, completing his diploma thesis with distinction and his doctoral thesis with *magna cum laude*. In 1999, he joined Hoffmann · Eitle and has been practicing as a registered German and European Patent Attorney since 2003. He was appointed partner of the firm in 2009. Dr. Disser has over 10 years of experience in advising clients in a variety of chemical and pharmaceutical technologies and covering all aspects of patent law, including drafting and prosecuting patent applications, opposition and appeal proceedings before the European Patent Office (EPO) and the German Patent and Trademark Office (GPTO), and nullity proceedings before the German Patent Court and the Federal Court of Justice. Dr. Disser frequently advises clients in validity and infringement matters.

Dr. Leonard Werner-Jones : Dr. Werner-Jones completed his B.A. in biology at Dartmouth College (USA) with high honors in 1991and went on to complete his doctoral thesis with *magna cum laude* at the Max-Planck-Institute of Neurobiology in Munich in 1998. He then worked as a scientist and faculty member at the University of California/San Diego (UCSD) researching nerve regeneration. During his tenure as a research scientist, Dr. Werner-Jones published numerous scientific publications and was the recipient of several international research awards and grants. Dr. Werner-Jones joined Hoffmann ·Eitle in 2004 and is practicing as a registered German and European Patent Attorney since 2009. As a German Patent Attorney, Dr. Werner-Jones advises clients on validity and infringement matters and focuses on nullity complaints before the German Federal Patent Court and the Federal Court of Justice. As a European Patent Attorney, his practice focuses on examination, opposition, and appeal proceedings before the European Patent Office with a technical focus in biotechnology, in particular neurobiology, immunology, cell biology, molecular biology and genetic engineering.

Mr. Tarun Khurana: Mr. Khurana focuses on Patent Preparation, Prosecution, Litigation, and Valuation related issues and represents IP portfolio of over 750 Indian and Global Corporates. Tarun brings a practice of over 9 years in the IP domain and has helped numerous US and European Patent Attorneys in providing Patent Support Services including Patentability Searches, Invalidation Searches, FTO, Infringement Analysis, Patent Preparation and Responding to Office Actions. Tarun represents a number of Fortune 500 Corporates and is involved in significant infringement and nullity proceedings. Tarun has a Bachelors in Engineering from Pune University, Masters in Software Systems from BITS Pilani, Bachelors in Law, and MBA from IIM Lucknow. Tarun is a member of AIPPI, APAA, INTA, TIE, and LES.

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.

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. Prior to joining Sughrue Mion, Ms. Kokabi also served at the U.S. Patent and Trademark Office as an Examiner.

Renita S. Rathinam : Rathinam did her B.S. Biology, with honors in the year 2000 from Emory University, M.S. Biochemistry and Molecular Biology with honors, 2004 from Georgetown University and J.D. from University of North Carolina School of Law. Rathinam practises in District of Columbia and at U.S. Patent and Trademark Office. Rathinam has served as litigation counsel in matters involving the chemical, pharmaceutical and mechanical arts and has significant experience in nearly all pre-trial, trial, and post-trial aspects of patent litigation. Central to Ms. Rathinam's practice is Hatch-Waxman Act analysis, and as such she has represented a number of pharmaceutical companies in ANDA/NDA related actions. She also engages in pharmaceutical/biotechnology patent infringement and validity opinion practice and counseling particularly 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.

Mr. Michael R. Dzwonczyk : Michael 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. 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 numerous 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 freedom-to-operate analysis. He did his Post-doctoral Fellow from National Institute of Health at New York University.

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 Corporates and Global Law Houses. IIPRD has been established precisely to assist the business houses in strategizing their growth by leveraging their IPR's through effective Creation, Promotion, Protection, and Commercialization of IP. IIPRD has been a part of large number of Out-Licensing deals for technology companies in Pharmaceutical and Hi-Technology domains such as NCE's, Formulations, and Process Patents in Pharma domain and Telecommunication/Network and Green Technologies. IIPRD has a legacy of twelve 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.

HOFFMANN · EITLE

Hoffmann · Eitle, founded in 1892, is not only one of the oldest but also one of the largest intellectual property law firms in Europe with a team of about 100 professionals and more than 300 total staff. The professionals include patent attorneys, attorneys-at-law and technical specialists. Hoffmann · Eitle is consistently ranked as a top tier firm in intellectual property in relevant lawyers' handbooks such as Chambers (Europe) and The Legal 500 (Europe and Germany). In 2010, Hoffmann · Eitle received the JUVE award as the German Firm of the Year in intellectual property and patent law. Hoffmann · Eitle handles all technological fields and legal aspects of intellectual property law. The firm has earned its excellent reputation by maintaining very high standards over decades, as is best illustrated by its success in international and pan-European prosecution work and in the litigation of many intellectual property rights for numerous companies ranging from small and medium-sized companies to major international corporations. Based in Munich and London, Hoffmann · Eitle is able to provide competent advice on the two most important (and intrinsically different) legal systems in Europe. With an office also in Milan and having, in addition to German and British patent attorneys, Italian, Dutch, Belgian and Spanish patent attorneys in its team of professionals, Hoffmann · Eitle is able to cover several important national European jurisdictions as well.

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 DNAto 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.

KHURANA & KHURANA, ADVOCATES & IP ATTORNEYS

Khurana & Khurana is more than a full service IP Law firm and is among the youngest Indian IP Law firms to have been ranked and recommended by Legal 500 and Managing IP. K&K was formed in the year 2006 with the very focus of providing End-to-End IP Legal Services along with its Sister Concern IIPRD, which supplement each other in order to provide end-to-end services to the corporate world in the IP Field. K&K and IIPRD, through their team of over 40 IP Attorneys and Practitioners, 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. 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 today represents global Corporates across geographies and technology domains and helps then successfully enforce, litigate, and protect their IP Portfolio in India.