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MAGAZINE PARTNERS



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INSTITUTE OF INTELLECTUAL PROPERTY RESEARCH AND DEVELOPMENT

PRESENTS

INTERNATIONAL SYMPOSIUMS FOR

R&D SCIENTISTS & IP PROFESSIONALS OF PHARMACEUTICAL, BIOTECH & CHEMICAL INDUSTRIES

AND

BUSINESS DEVELOPMENT PROFESSIONALS OF PHARMACEUTICAL, BIOTECH & CHEMICAL INDUSTRIES

WITH SUPPORT OF

SUGHRUE MION PLLC (USA)
&
CANTOR COLBURN LLP (USA)
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BARDEHLE PAGENBERG (Europe)
&
FUKAMI PATENT OFFICE (Japan)
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NAKAMURA & PARTNERS (Japan)
&
KHURANA & KHURANA (India)

SCHEDULE

Three Days Symposium for R&D
Scientists & IP Professionals from 5-
7th March 2013 at Chancellor-I, Hotel
Hilton Mumbai (Andheri East)

Two Days Symposium For Business
Development and Licensing
Professionals from 5-6th March 2013
at Chancellor- II, Hotel Hilton
Mumbai (Andheri East)

STRATEGIES FOR MANAGING PHARMACEUTICAL, BIOTECH & CHEMICAL PATENT PORTFOLIO; THE BEST WAY FORWARD

WHO SHOULD ATTEND

THREE DAYS SYMPOSIUM

Research & Development Scientists, IP
Managers, Patent Agents & Attorneys in the
field of Practice, Patent Litigators,
Professionals in Legal Domain related to
Pharma, Biotech and Chemical Industries

TWO DAYS SYMPOSIUM

Business Development, Legal Counsellor,
Licensing and Marketing Professionals in
Pharmaceuticals, Biotech and Chemicals
Industries

ABOUT THE SYMPOSIUMS

With Patents becoming a core part of existing economic ecosystem, particularly for Pharmaceutical, Biotech, Chemical & 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 team but even more importantly for R&D Scientists and Business Development Professionals, so as to minimize the efforts in Patent Development and to maximize the commercial gains. It is therefore 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 threat 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, 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 Europe, Japan and United States. It is in this direction that the International Symposiums is being organized to impart comprehensive knowledge to understand the nitty-gritty of Patent Regime.

HOW THE SYMPOSIUMS ARE UNIQUE

These Symposiums feature presentation of all important patent issues, as mentioned in this brochure, related to two different groups i.e. Business Development Professionals on one hand and R&D Scientists & IP Professionals on the other hand. Both these symposiums for different groups would run concurrently in different Conference Halls with the R&D Symposium taking place from 5-7th March 2013 and Business Development Symposium taking place from 5-6th March 2013 at two different halls of Hotel Hilton. The speakers are a unique gathering of Patent Attorneys, Legal Counsels, and also include experts from the Commercial domain for Business Development Group, who have extensive years of experience in their professional fields. These Speakers will put across to the delegates a real insight of Patent Laws & Practices, and Commercial perspectives as prevalent and practiced in Europe, Japan, United States, and India. The Workshop will provide an opportunity to receive first-hand information including recent judgments on various issues from the experts in the fields.

SCHEDULE

Registration Fees:

For 3 days Symposium for R&D and IP Professionals:

Rs. 15000/- Per Delegate (If 4 or more delegates are nominated, the delegate fees would be Rs. 12000/-)

For Foreign Delegates: USD 400 Per Delegate

For 2 days Symposium for Business Development Professionals:

Rs. 10000/- Per Delegate (If 3 or more delegates are nominated, the delegate fees would be Rs. 8000/-)

For Foreign Delegates: USD 300 Per Delegate

Please Forward the Delegate Fees with the following details: Name, Organization, Designation, and Contact Details along with the cheque drawn in favour of "M/S IIPRD" UCO Bank A/C Number 19620210002476" at :

Mr. Tarun Khurana

Institute of Intellectual Property Research & Development

S/19-22, GNS Plaza, UPSIDC Site-IV, Kasma Road, Opp Radisson Hotel, Greater Noida-201308, UP, India.

For any query contact:

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SYMPOSIUM FOR R&D SCIENTISTS & IP PRACTITIONERS

DAY-1 [US AND JAPAN SCENARIO]

- 0930-1115: Strategies for R&D Scientists for conducting prior art searches and effective patent drafting in the chemical, drug delivery and formulation arts for the best protection globally.
- 1130-1310: Role of patent infringement in R&D; FTO analysis; Claim interpretation; Mechanics of drafting FTO opinions and types of FTO opinions; Integrating FTO landscape assessments into the product development process
- 1310-1400: Lunch
- 1400-1515: Recent Developments in Patentability standards at the USPTO in view of the recent case laws, Obviousness issues related to active pharmaceutical ingredients; impact of recent post KSR court decisions on obviousness issues of active ingredients, drug delivery and formulations;
- 1530-1630: Strategies for successful disclosure of inventions in patent specifications in the US; determination of written description and enablement requirements; Strategies for efficiently obtaining patents; Strategies for handling a restriction or a lack of unity requirement
- 1630-1730: Patentability and Infringement Considerations in Japan; Invalidation of Japanese patent and Claim Interpretation, comparison between Japan and US patent law where applicable; FTO procedure and infringement analysis; amendments in Patent Act

DAY-2 [EP AND JAPAN SCENARIO]

- 0915-1115: Recent trends in pharmaceutical patent law and practice at the EPO; sufficiency of disclosure requirement; major differences between the EPO and USPTO patentability standards; how to effectively understand and respond to communications from EPO examiners
- 1130- 1300: EPO Opposition and Appeal Procedure; best strategies for conducting freedom-to-operate for chemical synthetic processes; enforceability of patents; impact of the Eli Lilly v HGS decision; Second medical use claims; Patenting Diagnostic methods in Europe
- 1300-1345: Lunch
- 1345-1500: Overview of European Generic Drug Approval Processes; Supplementary Protection Certificates (SPCs); Recent Decisions in SPC matters; Paediatric SPC extensions; SPC extensions for combination products; Data Exclusivity
- 1515-1730: Examination Guidelines in pharmaceutical fields in Japan; Japanese Patent trend in NDSS; Contributory and willful infringement, patent term extension in Japan, Japanese pharmaceutical R&D Best practices to get robust Patent

DAY-3 [US SCENARIO-ANDA]

- 0930-1030: Primer on patent and regulatory backdrop for the clear in-depth understanding of the Hatch Waxman litigation; understanding the interplay of the USPTO and FDA in the patenting of drugs; Exclusivities; Bioequivalence; Orange Book Listings; ANDA approval process; etc.
- 1030-1130: Best Strategies for Generic product development lifecycle management from the perspective of R&D group; patenting of bioequivalence characteristics; extended-release drug products; formulation development
- 1145-1300: Evaluating new trends in validity challenges including extended and delayed release formulations; obviousness-type double patenting and litigation strategies based on prior art obviousness analysis; Understanding the significance of Novo Nordisk v. Caraco
- 1400-1545: An update on recent Para-IV disputes; Strategies used for litigating different types of listed claims, such as claims to compounds, formulations, methods of treatment etc.; Reassessing Paragraph IV Strategies for Method of Treatment Patents in View of Recent Decisions Regarding Inducement and Divided Infringement;
- 1600-1730: Key provisions of the America Invents Act (AIA); influence of AIA on Orange Book listings; Assessing the impact of AIA on Paragraph IV Litigation

SYMPOSIUM FOR BUSINESS DEVELOPMENT PROFESSIONALS

DAY-1 [EP SCENARIO]

0930-1130: Introduction to Patents (top view of Novelty, Inventive step); Patent prosecution basics, Patent fencing and Patent Portfolio Management by EP and Japanese Speakers

1145-1315: Basic Overview of Patent Enforcement; Patent challenges, Patent infringement and Patent Litigation procedures in EP in the chemical and pharmaceutical arts.

1315-1400: Lunch

1400-1500: Basic understanding of conducting Freedom to operate and Due Diligence searches

1500-1600: Patent and Licensing practices in Japan, how best the Indian Pharma Companies can take advantage of present Japanese Drug Market and Patent scenario

1615-1730: Introduction to Global Trademark scenario, Brand Management and Trade Mark assignment from Business perspective & important elements of Licensing of Pharma Patent.

DAY-2 [US SCENARIO]

0930-1115: Introduction to Patents (top view of Novelty, Inventive step); Patent prosecution basics, Patent fencing and Patent Portfolio Management by US Speakers

1130- 1315: Introduction to Patent infringement in the chemical and pharmaceutical arts in US and how effectively conducting of Freedom to operate and Due Diligence searches help to prevent infringement.

1315-1400: Lunch

1400-1515: Overview of Patent Enforcement; Patent challenges and Litigation procedures in US

1530-1730: Strategies for scouting partners in Japanese Markets, Best practices while negotiating Licensing Deals, Drafting and Executing Agreements in Japan, through case studies

ABOUT THE 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 counseling in a variety of technologies with focus on chemical and pharmaceutical arts. Chid has prepared and prosecuted over 100 applications for a leading research laboratory.



Steven M. Coyle: Steve Coyle is a Partner and trial lawyer at Cantor Colburn with nearly 20 years of experience in litigating and trying complex disputed matters, and has specialized in patent and all varieties of IP litigation for the past 15 years. Steve's areas of focus include ANDA and Hatch-Waxman litigation, and is the Group Leader of Cantor Colburn's Pharmaceutical Litigation Practice. Steve has represented clients in a variety of other patent and IP matters, as both plaintiffs and defendants, in courts as well as in alternative dispute resolution proceedings such as arbitrations and mediations.



Jeffery Arnold: Partner at Cantor Colburn LLP, is an IP attorney with more than 20 years' experience and has a M.S. in biochemistry. Jeff concentrates his practice on generic pharmaceuticals, to include litigation and validity, infringement, and freedom-to-operate opinions in support of ANDAs and launch-at-risk evaluations/opinions. Further, Jeff counsels his clients on strategies for managing and protecting patent portfolios; prepares validity, infringement, freedom-to-operate, and patentability opinions; represents clients in all aspects of patent prosecution; and supports numerous litigation matters in addition to his generic pharma practice.



Tarun Khurana: Tarun is a Partner at IIPRD and Khurana & Khurana and with his over 10 years of experience in a range of complex Patent matters is known for his knack in Patent Drafting, Infringement, Invalidation, and Protection strategies and is a counsel to a range of Fortune 500 and Start-up companies in High-Technology domain owing to his BE and MS in Software along with his LLB, and MBA from IIM Lucknow. Tarun is highly recommended by bodies such as Legal 500 and Managing IP and is an active member of APAA, AIPPI, LES, and INTA.



Leslie-Anne Maxwell, Ph.D. : Anne Maxwell, Counsel at Cantor Colburn LLP, provides all aspects of patent representation to clients working in chemical and life science research. Anne has more than 10 years' experience drafting patents and prosecuting US and non-US patents in the areas of small molecule pharmaceuticals, drug delivery and formulations, chemical processes, among other allied. Anne also prepares invalidity and non-infringement opinions in ANDA litigation. Prior to joining Cantor Colburn Anne worked as a patent agent and chemist at Neurogen Corporation.



David E. Rodrigues, Ph.D. Dave Rodrigues, Partner at Cantor Colburn LLP, has 11 years' experience with increasing responsibility in patent preparation and prosecution, due diligence, opinion work, including noninfringement, invalidity, and right-to-practice. Prior to becoming a patent attorney, he worked as a Plant Chemist for Armstrong World Industries and as a Pilot Plant Manager for General Electric Silicones and the General Electric Global Research Center. He is the lead partner for the technology transfer office of a major research university and for other clients with sophisticated technology and IP portfolios.



Toshio Nakamura : Toshio is a Japanese patent attorney in Fukami Patent Office, p.c. He has over 20 years of experience in patent prosecution and litigation covering general chemistry, pharmaceuticals, biotechnology, patent term extension, etc. He obtained his PhD in chemistry from Tokyo University in 1985. Before joining Fukami Patent Office in 2010, he worked for Sumitomo Pharmaceuticals, Co., Ltd. and Mitsubishi Tanabe Pharma Corporation.



Satsuki Ichikawa: Satsuki is a Partner and Patent Attorney in Chemical Section of Nakamura & Partners. Her main practices include Patent Infringement, Nullity Actions, Patent Clearance Searches including opinions regarding patentability and infringement. She has specialization in chemistry, pharmaceuticals, industrial polymer compounds, foods, fibers, and medical devices. She holds a degree of Ph.D from Keio University, Department of Applied Chemistry. She joined Nakamura & Partners in 1995.



Thomas Friede: Thomas is a Partner, European Patent Attorney and German Patent Attorney at Bardehle Pagenberg in Munich, Germany. He holds a Ph.D in Biochemistry and concentrates on Life Sciences and pharmaceutical inventions. His practice encompasses patent prosecution before the EPO and patent litigation before the District Courts and the Federal Patent Court. He has particular litigation experience with drug-eluting stents, diagnostic assays, cosmetics, vaccines and antibodies. Thomas is recommended for patent prosecution and patent nullity matters by Intellectual Asset Management (IAM).



Wolfgang Bublak: Wolfgang is a partner at Bardehle Pagenberg, his practice covers prosecution and litigation of patents and utility models including opposition proceedings and national patent revocation actions, infringement litigation and licensing. His technical expertise encompasses organic and inorganic chemistry as well as biochemistry. Wolfgang represents major European and international corporations in patent opposition and invalidation proceedings and as lead patent attorney in complex patent infringement litigation.



Vinod Khurana: Vinod has been in the field of commercial legal finance for the last 39 years. Vinod started his own practice in Intellectual Property and Investigative Audit in the late Nineties. Vinod is Executive Director at the IIPRD. He is also the President of the Institute of Forensic Accounting and Investigative Audit and is Senior Partner at an IP Law Firm, Khurana & Khurana Advocates & IP Attorneys and Litigates Fraud/ Infringement related matters. Vinod has been speaking on various Intellectual Property and Fraud Investigation matters at more than 150 National & International forums in India and Abroad.



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.



ABOUT THE ORGANIZERS

IIPRD: IIPRD is among India's leading IP Consulting and Licensing Firms 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, Research, Litigation, and Prosecution Support Services to top Global Corporates and International Law Firms. IIPRD has been established precisely to assist the business houses in strategizing their growth by leveraging their IPR's through effective Creation, Protection, and Commercialization of IP. IIPRD has a legacy of over 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 Corporates.

Sughrue Mion: Sughrue Mion is one of the world's leading intellectual property law firms managing traditional and non-traditional intellectual property rights, 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. 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. 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.

Cantor Colburn LLP: Cantor Colburn is one of the largest full service IP law firms in the U.S.A. providing exceptional counsel and representation to clients in litigation, patents, trademarks, and all areas of IP. Cantor Colburn LLP's Pharmaceutical Litigation Practice has successfully represented several generic drug companies in ANDA and Paragraph IV patent challenges. Experienced and highly skilled, Cantor Colburn helps its clients- including Fortune 100 companies, privately held companies, select high-tech start-ups, and universities- protect and defend their valuable IP.

Bardehle Pagenberg: Bardehle Pagenberg is one of the largest IP firms in Europe representing clients in application proceedings and in litigation 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. Bardehle Pagenberg's patent attorneys and attorneys-at-law have long experience and expertise in protecting a wide variety of technical inventions.

Fukami Patent Office p.c: Fukami Patent Office was founded by Mr. Hisao Fukami in 1969, is based in Osaka, Japan and also has its branch office in Tokyo. First specialization in the electrical field, Fukami Patent Office has gradually expanded to cover all major technical areas and is truly a full-service IP firm. Clients of Fukami Patent Office include some of the largest and most prestigious clients in various business and technical fields. Currently, the office has a total of 239 staff members including 74 attorneys. By size, Fukami Patent Office ranks as the 6th largest in Japan.

Nakamura & Partners: Nakamura & Partners is a leading international patent and law firm founded in 1914. Nakamura & Partners has approximately 180 staff members, including about 70 patent attorneys, about 20 attorneys-at-law and about 30 partners. Nakamura has been consistently awarded the "Prosecution & Contentious IP Firm of the Year" by Managing IP including various others awards by Legal 500 and AsiaLaw IP Awards. Nakamura's aim is to provide the highest level of professional services in IP rights and legal matters relating thereto, to comply with the requests of clients and to construct an excellent and long-lasting trustworthy relation with their clients.

Khurana & Khurana, Advocates & IP Attorneys: Khurana & Khurana is among the leading full service IP Law Firms in India and has, in a short period of 6 years since establishment, gained repute and acknowledgment for its IP Contentious and Non-Contentious practice. K&K is among the youngest Indian Firms to have been strongly ranked and recommended by Legal 500 and Managing IP and through its team of Patent and IP Attorneys, represents numerous Corporates ranging from Fortune 500 and Start-up Companies, which span across technology domains. K&K is based in Delhi (Noida) and Pune and is an active member of AIPPI, INTA, APAA, LES, among other such international bodies.