December 7 - 8, 2009 | The Carlton | New York, NY

FOREIGN PATENT LAW & REGULATION

FOR THE U.S. LIFE SCIENCES PATENT PRACTITIONER

Strategies for Containing Costs and Maximizing IP Protection in the EU & Emerging Asian Markets

Featuring in-house insights from the following leading international life sciences companies:

Boehringer-Ingelheim
GlaxoSmithKline
Medtronic
Novartis
Novo Nordisk
Purdue Pharma
sanofi-aventis
Sanofi Pasteur
Schering-Plough

As well as counsel experienced in patent prosecution and litigation in the following countries:

Australia
Belgium
China
India
Italy
Germany
Japan
Korea
Netherlands
Singapore
Switzerland
United Kingdom

Patent counsel with extensive experience in prosecuting foreign life sciences patents, as well as litigating IP disputes overseas will provide you with insights for:

- **DEVELOPING** a strategic plan for deciding **when** and **where to file** your life sciences patents abroad
- **PROSECUTING** and filing life sciences and pharmaceutical patents in **emerging Asian markets**
- **NAVIGATING** unique issues that arise in the context of seeking **supplementary protection certificates** (SPCs) and **method of use/treatment claims** for your life sciences patents
- **ADDRESSING cultural idiosyncrasies** and **technical requirements** in various jurisdictions when developing your international patent litigation strategy
- **SELECTING** and managing a **multi-jurisdictional patent litigation team**
- **SEEKING damages** and pursuing available **remedies abroad** – knowing what you can (and cannot get) and where you can get it
- **ASSESSING** the impact of the **EC Sector inquiry** on global pharmaceutical patent life cycles

WORKSHOP

Mastering the Interplay Between Foreign Patent Law and Regulatory Requirements for Life Sciences Companies in the EU and Asia

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Increase your international life sciences patent IQ. Learn the "ins" and "outs" of foreign prosecution and litigation strategies that are unique to the life sciences industry.

As more and more life sciences companies are filing patents on a global scale as a matter of course, foreign patent prosecution and enforcement have become an increasingly important priority for U.S.-based patent and IP counsel. Still, with all of the day-to-day demands that come with overseeing and protecting a patent portfolio, it is difficult to stay up-to-speed on what the current status of the law is in the EU and emerging Asian markets, particularly in light of recent reform and restructuring initiatives that have taken hold in various countries overseas.

Come to this conference and gain cutting edge, *industry-specific* insights on how to develop a multi-jurisdictional patent portfolio management and litigation strategy for your company.

This event has been designed to provide in-house patent and IP counsel within the *pharmaceutical, biopharmaceutical, biotechnology* and *medical device* industries with a working knowledge of the current status of patent law in key foreign jurisdictions. A leading faculty comprised of experienced in-house counsel representing such multi-national companies as: **Boehringer Ingelheim, GlaxoSmithKline, Medtronic, Novartis, Novo Nordisk, Purdue Pharma, sanofi-aventis, Sanofi Pasteur, Schering-Plough**, as well as patent prosecution attorneys and litigation counsel from: **Australia, Belgium, China, India, Germany, Japan, Korea, Netherlands, Switzerland** and the **United Kingdom** will provide you with an in-depth overview of the unique issues that arise in the context of both prosecution and litigation outside the U.S.

Attend this event and enhance your understanding of the nuances of foreign patent prosecution and litigation that specifically apply to the life sciences industry. Don't miss this opportunity to network with the Who's Who of the foreign life sciences patent bar, as well as your peers as you discuss strategies for tackling the international patent challenges that lie ahead for the industry.

To complement your overall experience, attend the workshop session on **Mastering the Interplay Between Foreign Patent Law and Regulatory Requirements for Life Sciences Companies in the EU and Asia**. In this intense, hands-on workshop, foreign patent counsel experienced in navigating the intersection between patent and regulatory law will provide you with critical knowledge of the relevant requirements and applicable laws relative to obtaining both IP protection and regulatory approval.

Register now by calling **888-224-2480**, faxing your registration form to **877-927-1563**, or online at **www.americanconference.com/foreignpatentlaw**.

Who You Will Meet

Pharmaceutical, biopharmaceutical, medical device and biotechnology counsel and executives with the following titles:

- International Patent Counsel
- Patent Counsel
- Chief Patent/IP Counsel
- Director/Vice President of IP
- Patent Litigation Counsel
- Litigation Counsel
- Business Development

Outside counsel with expertise in:

- International patent practice and litigation
- Pharmaceutical, biotechnology and medical device patent law
- Patent prosecution

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MONDAY, DECEMBER 7, 2009

7:30 **Registration and Continental Breakfast**

8:00 **Co-Chairs' Opening Remarks**

Teresa Stanek Rea
Partner
Crowell & Moring LLP (Washington, DC)
President, American Intellectual Property Law Association (AIPLA)

James M. Gould
Legal Director - Global Patent Litigation
Schering-Plough Corporation (Kenilworth, NJ)

Prosecution

Each session on the first day of the conference will focus on providing you with advanced insights for strategically evaluating your life sciences patent portfolio in a manner that will optimize your IP protection abroad.

8:15 **Why Now?: Understanding the Importance of Developing a Global Strategy for Your Life Sciences Patent Portfolio**

Esther Kepplinger
Director, Patent Operations
Wilson Sonsini Goodrich & Rosati (Washington, DC)
Former Deputy Commissioner for Patent Operations, USPTO

Reza Green
Chief Patent Counsel
Novo Nordisk Inc. (Princeton, NJ)

Over the past few years, there has been a flurry of activity affecting patent protocols throughout the world. In Europe, filing fees are dramatically increasing thereby affecting the number of claims filed. There are also developments concerning claims analyses with respect to divisionals which are critical to ensuring the long term commercial embodiment of a patented drug/biological product. Meanwhile, China and India are in the infancy of their respective patent systems and causing uncertainty as to which protections will be afforded for life sciences inventions. Finally, the U.S. stands on the brink of patent reform which could more closely align our current system with that of the rest of the western world and a regulatory/patent regime for follow-on biologics that may differ significantly from the evolving European system.

Collectively, these developments coupled with the realization that most large life sciences companies are in fact multi-national entities or conduct trade on an international scale are proof that the world in essence is getting smaller and that it is critical to think of IP protection on an international scale. This session will explore the importance of thinking globally when devising patent strategies for your life sciences patent portfolio.

Foreign Patent Practice Fundamentals: Obtaining Patent Rights Internationally for Your Life Sciences Invention

9:00 **Evaluating Advantages and Limitations of Foreign Filing Conventions and Treaties**

Samson Helfgott
Director of Patents
KattenMuchinRosenman LLP (New York, NY)

Esther Kepplinger
Director, Patent Operations
Wilson Sonsini Goodrich & Rosati (Washington, DC)
Former Deputy Commissioner for Patent Operations, USPTO

Moderator:

John P. White
Partner
Cooper & Dunham LLP (New York, NY)

- The Paris Convention
  - identifying what rights the Paris Convention confers on those seeking patents in foreign jurisdictions
  - taking full advantage of the right of priority
  - what countries are parties to the treaty?
- Patent Cooperation Treaty (PCT)
  - obtaining consistent examination of your life sciences patents by effectively utilizing the PCT
    - complying with specific procedures under the PCT
  - how to construct your claims
  - strategies for using the PCT effectively and efficiently
    - yielding the maximum benefit from filing while also obtaining the claims you want
- Patent Prosecution Highway (PPH)
  - how to use the PPH to your advantage
  - which countries are participants
    - reciprocity?
  - streamlining prosecution strategies for life sciences patents

10:00 **Foreign Patent Offices: Exploring Filing and Prosecution Protocols**

Dr. Peter Klusmann
German and European Patent Attorney
Hoffman Eitle (München, Germany)

Grace L. Pan
Partner
Frommer Lawrence & Haug LLP (New York, NY; Tokyo, Japan)

John P. White
Partner
Cooper & Dunham LLP (New York, NY)

Dr. Francesco Fiussello
Italian and European Patent Attorney
Studio Torta (Torino, Italy)

- European Patent Office (EPO)
  - revising your international search and examination reports in light of the new EPO rules on divisional applications taking effect in April 2010
    - understanding how this impacts pharmaceutical patents and how it compares to U.S. divisionals and continuations
  - adjusting your filing budget to account for recent changes to claim fees
    - are dependencies an option in your application?
    - evaluating which claims can successfully be made for life sciences products
  - determining whether or not the country where you are filing a patent requires translation of grants under the London Agreement
- Filing in European countries not party to the European Patent Convention (EPC)
  - studying the prosecution differences in these countries
- Japan Patent Office (JPO)
  - navigating the filing process at the JPO
  - preparing for and filing an infringement or PI action as a plaintiff
  - best defenses to assert as a defendant during invalidation trials
- World International Patent Organization (WIPO)

11:15 **Morning Coffee Break**

11:30 **Filing and Prosecuting Life Sciences & Pharmaceutical Patents in Emerging Asian Markets**

Kyumin Kevin Lee
Foreign Attorney
Kim & Chang (Seoul, Korea)

Jiancheng Jiang
Managing Partner
Peksung Intellectual Property Ltd. (Bejing, China)

Hari Subramanium
Managing Partner
Subramaniam, Nataraj & Associates (New Delhi, India)

- China
  - incorporating recent changes to the Patent Law regarding:
    - the standards for obtaining patents
    - patent enforcement and pre-trial preservation of evidence
    - using a genetic resource to achieve a gene-related invention
    - exploring China's current treatment of U.S.-based pharmaceutical patent applications
  - recognizing geographic regions in China not covered by Chinese patents
  - determining whether inventions made in China must be filed in China first
- India
  - handling difficulties in achieving inventive step and prevailing over India's vague claim rejections
  - identifying and managing challenges presented by India's pre-opposition procedures
  - drafting Indian patent applications in accordance with local standards
  - understanding how India's recognition of primary patents only is impacting U.S. pharmaceutical patents applications and patent strategies
  - exploring innovation in the Indian pharmaceutical market
    - new competition for generics?
- Korea

12:30 **Networking Lunch**

1:30 **Guidelines for Evaluating Standards of Patentability and Selecting the Best Jurisdictions in Which to File Your International Life Sciences Patent**

Dr. Edouard G. Lebel
Associate Director
Boehringer Ingelheim Pharmaceuticals Inc. (Ridgefield, CT)

Grace L. Pan
Partner
Frommer Lawrence & Haug LLP (New York, NY; Tokyo, Japan)

Kristian Robinson
Director & Head of Chemical & Life Science Patent Department
Ella Cheong Spruson & Ferguson (Singapore)

- Selecting which country to file in
  - which countries should you always/sometimes file in?
  - special considerations for pharmaceutical patents in emerging Asian systems
  - conducting a pre-filing review in order to determine whether or not foreign patent holder's rights are enforceable in the jurisdiction in which you plan to file
- Best practices for filing a life sciences patent in your country of choice – evaluating which method works best
  - filing directly in the country of choice
  - filing through one of the established conventions
  - filing regionally
- Exploring the different standards of patentability for pharmaceutical and biological patents in various jurisdictions – focusing on Europe and Asia

2:30 **Strategies for Successfully Obtaining Method of Use/Treatment Claims**

Bert Oosting
Head, Intellectual Property & Information Technology Group, Amsterdam Office
Head, Pharmaceutical Group, Amsterdam Office
Lovells LLP (Amsterdam, Netherlands)

George W. Schlich
European Patent Attorney
Schlich & Co (West Sussex, United Kingdom)

Obtaining method of use/treatment claims, also known as Swiss type claims, is an ongoing challenge in filing pharmaceutical patents in Europe as these claims are very complicated and nuanced. This session will provide you with best practices for acquiring these claims, not only in Europe, but also in other emerging markets where they have taken hold.

- Understanding the origin of Swiss type of use claims and evaluating their impact on subsequent medical use/indication of previously identified compounds
- Drafting your claims language in a flexible manner that will allow you to incorporate subsequent or yet unknown uses of known compounds
- Exploring the concept of novelty and inventive step vis-à-vis the viability of treatment claims in Europe
  - comparing inventive step in Europe to the U.S. concept of obviousness under *KSR*
- Learning to balance the language covering method of treatment with the novelty and inventive step of the invention
  - strategies for drafting claims that will be patentable in foreign jurisdictions
- Recognizing the difference between written description and best mode requirements in the U.S. vs. written description and sufficiency of disclosure in the EU
- Meeting the standards of description and disclosure in the EU without a showing of best mode

3:15 **Afternoon Refreshment Break**

3:30 **Navigating the "Ins" and "Outs" of Opposition Practice in Europe and Asia**

Hari Subramanium
Managing Partner
Subramaniam, Nataraj & Associates (New Delhi, India)

Balu Gupta, Ph.D., J.D. ***(Invited)***
Associate Vice President/Head, CNS Group
US Patent Operations
sanofi-aventis US Inc. (Bridgewater, NJ)

Dr. Peter Klusmann
German and European Patent Attorney
Hoffman Eitle (München, Germany)

- Understanding which challenges can legitimately be made to a pharmaceutical patent under current opposition practice protocols in Europe and Japan
  - exploring the application of opposition practices in China, India and Korea
- Crafting a pre-opposition checklist
  - how will the file history be looked at from an opposition standpoint?
    - how will the U.S. file history be viewed?
  - ensuring that a comprehensive prior art search is conducted during prosecution to safeguard your patent's validity during opposition proceedings

4:30 **Supplementary Protection Certificates (SPCs): Strategies for Successfully Extending The Patent Term on Your Life Sciences Invention**

Dr. Klemens Stratmann
German and European Patent Attorney
Hoffman Eitle (München, Germany)

Dr. Frank-Erich Hufnagel
Partner
Freshfields Bruckhaus Deringer LLP (Düsseldorf, Germany)

- Meeting the requirements to obtain an SPC
  - tips for maximizing the patent extension obtained under an SPC for human medicinal products
    - weighing the pros and cons of seeking a pediatric extension
    - obtaining a zero term or SPC or quasi patent term extension
  - determining what extension term is best for your product based on an assessment of the type of rights you will be granted
  - discussing whether or not a white paper can be used to obtain an SPC
- Contemplating whether or not a new SPC can be obtained for new combinations, isomers, etc.
- Identifying what (if any) alternatives exist for obtaining an SPC when seeking to extend the patent term on your product
- Evaluating differing standards for obtaining an SPC on a country-by-country basis
- Considering issues unique to seeking an SPC when the original Marketing Authorisation (MA) was granted in a country that is not part of the European Economic Area (EEA), i.e. Switzerland
- Obtaining a springboard injunction for marketing and distribution after patent expiry in case of offering and inclusion in pricelists before patent expiry

5:15 **Conference Adjourns to Day Two**

TUESDAY, DECEMBER 8, 2009

8:00 **Continental Breakfast**

8:30 **Co-Chairs' Remarks**

Enforcement/Litigation

Building on the presentations of Day One, the sessions on Day Two of the conference will provide you with practical, hands-on solutions for most effectively enforcing and litigating your life sciences patents across the globe.

8:45 **Balancing Competing Antitrust and IP Interests: Assessing the Impact of the EC Pharmaceutical Sector Inquiry on the Exercise and Defense of Patent Rights**

Morag Peberdy
Of Counsel
Covington & Burling LLP (London, England)

David Rosenberg *(Invited)*
Vice-President, Corporate IP Policy
GlaxoSmithKline (London, England)

Never before has the interface between IP and antitrust laws across the globe become more pronounced. For over a decade in the U.S., the FTC has scrutinized the relationship between brand name pharmaceutical innovation and delayed generic entry. Recently, China passed its own antitrust law and has launched an investigation into the competing interests between IP and antitrust law through a tech sector review. However, no action has made the fine and sometimes dangerous line between IP and antitrust laws more apparent than the EC's Pharmaceutical Sector Inquiry.

In January 2008, the European Commission conducted a series of pre-dawn raids on several global pharmaceutical companies as part of a competition inquiry to determine whether industry practices curtailed innovation and generic product entry. Last November, the Commission released a preliminary report on its findings from this inquiry and determined that "there is evidence that originator companies have engaged in practices with the objective of delaying or blocking market entry of competing medicines." The final report, released in early July 2009, confirms their preliminary findings and goes a step further, outlining further investigations the Commission plans to take in order to curtail future anti-competitive activity. In some respects the final report was more balanced than the interim report. However, the final report gives very little guidance on how to navigate the sometimes hazardous intersection of intellectual property and competition law, and much uncertainty remains as to which activities are legal, and which are not.

This session will explore how the Report is likely to influence the future exercise and defense of patent rights, especially in the context of patent litigation, patent settlements and pharmaceutical life cycle management in the EU, as well as the Report's global implications in the context of antitrust enforcement relative to pharmaceutical patent life cycle management in the U.S. and Asia.

9:30 **Morning Coffee Break**

9:45 **Considerations for U.S. Life sciences Companies When Filing Patent Suits Abroad and Selecting Foreign Litigation Counsel**

Jeffrey H. Hohenshell
Senior Patent Attorney
CardioVascular, Medtronic, Inc. (Minneapolis, MN)

Juergen Dressel
Head of Litigations Patents
Novartis Pharma AG (Basel, Switzerland)

Gregory A. Madera
Principal
Fish & Richardson P.C. (Boston, MA; Minneapolis, MN)

Before filing a patent suit internationally, there are some vital questions that in-house counsel must consider, the least of which is deciding when and where to sue and which counsel to choose. The choices may not be so apparent. During this session, learn which questions to ask before bringing suit and choosing your counsel.

- Why are we suing and what are we seeking?
  - damages
  - injunction
  - protective order
  - seizures
  - declaratory judgment
- Deciding where to sue – making a preliminary assessment of available validity and infringement proceedings in various jurisdictions
  - identifying jurisdictions in which life sciences patents are most strongly upheld
- Identifying what type of life sciences invention is at the heart of the dispute
  - a process
  - product or composition
  - "new use" or pioneer invention
- Exploring pre-litigation opportunities for attacking and defeating your competitor's patents
- Conducting a foreign infringement analysis to determine your position prior to engaging in litigation
  - determining whether the life sciences patent in question is worth defending abroad - does it have both commercial strength and longevity?
- Considering and accounting for the effect pending litigation could have on:

- your company's reputation and profits in the U.S. and abroad
- foreign corporate operations, particularly your legal and R&D departments

- Conducting a foreign infringement analysis to determine your position prior to engaging in litigation
- Assessing costs and evaluating potential accomplishments of litigating in various foreign jurisdictions
- Seeking out competent foreign patent litigation counsel who are both knowledgeable and in tune with the inner workings of U.S. life sciences companies
- Considering available incentives to avoid litigation in certain jurisdiction
  - data exclusivity
  - higher profit

11:00 **Successfully Seeking Injunctive Relief for Your Life Sciences Patent: Strategies for the EU and Asia**

Mustafa Safiyuddin
Chairman
Legasis Partners (Mumbai, India)

Kevin Mooney
Partner
Simmons & Simmons (London, England)

Connie Carnabuci
Head, Asia Intellectual Property/Information Technology
Freshfields Bruckhaus Deringer LLP (Hong Kong, China)

- Meeting the requirements for obtaining an injunction
- Assessing whether the injunction will provide the sought after relief
- Preliminary vs. permanent injunctions in Europe and Asia
  - special considerations for Japan
  - exploring the concept of injunctive relief in China and India
- Exploring key concerns relative to:
  - timing
  - merits
  - balance of convenience
- Pan-European injunctions

12:30 **Networking Lunch**

Litigating the Multinational Life Sciences Patent Dispute

Special Section Moderator:

James M. Gould
Legal Director - Global Patent Litigation
Schering-Plough Corporation (Kenilworth, NJ)

1:30 **Organizing and Managing Your Foreign Patent Litigation Team and Strategy**

Philip C. Strassburger
Vice President, Intellectual Property
Purdue Pharma L.P. (Stamford, CT)

Benoît Strowel
Head of Intellectual Property, Europe
Howrey LLP (Brussels, Belgium)

Frank A. Smith
Global Head of OTC Patents
Novartis Consumer Health, Inc. (Parsippany, NJ)

John Parrish *(Invited)*
Vice President, Intellectual Property
Sanofi Pasteur, Inc. (Swiftwater, PA)

- Building an international "dream team" to accomplish your litigation objective
  - learning to delegate while still maintaining control
    - knowing when to use your own judgment even when foreign counsel advises to the contrary
  - understanding the role of the individual trial counsel
- Overcoming cultural barriers within your team that may affect your strategy
  - dealing with foreign perceptions of the threat of impending litigation
  - considering the impact on your litigation strategy in a civil law vs. a common law jurisdiction
- Maintaining a consistent strategy when litigating disputes over the same patent in different jurisdictions
- Managing multi-jurisdictional impediments that can disrupt your litigation strategy
- Handling varying results in different jurisdictions
- Evaluating costs and remaining within your litigation budget
  - focusing your budget on patents that are critical to your business

2:30 **Understanding The Mechanics of Conducting and Seeking Discovery in Foreign Jurisdictions**

Kevin W. McCabe
Director
Sterne, Kessler, Goldstein & Fox P.L.L.C. (Washington, DC)

Kristof Roox
Partner
Crowell & Moring LLP (Brussels, Belgium)

- Exploring methods for obtaining an order to pursue discovery in various jurisdictions
- Evaluating what forms of discovery are available in the jurisdiction in which you are litigating
  - civil law vs. common law
  - interrogation and cross examination
  - seizures vs. preservation of evidence
- Seeking discovery on the basis of a foreign pharmaceutical patent
  - working around unique issues that may arise when pursuing discovery of information only attainable from a non-U.S. office or employee
  - complying with various local and country-specific requirements when seeking discovery of information in various jurisdictions
- Becoming familiar with foreign discovery timetables
- Maintaining a reasonable discovery budget
- Determining whether or not evidence obtained in one country can be:
  - used to pursue discovery in another country
  - used as evidence in a parallel or separate but related suit in another country

3:15 **Afternoon Refreshment Break**

3:30 **Obtaining, Calculating and Evaluating the Scope of Available Damages Abroad**

Dr. Andreas von Falck
Partner
Lovells LLP (Dusseldorf, Germany)

Liz Cohen
Partner
Bristows (London, England)

- Considering whether or not punitive damages are allowed and how your litigation strategy may change if not available

- Understanding what concrete damages are and when you can seek them
- Obtaining lost profit and reasonable royalty damages
  - how to prove and calculate – interest and conveyed sales
  - providing timely disclosure of the patentee's application
  - establishing loss of business chances in a foreign life sciences market
  - accurately determining what the infringer's profits are
- Verifying compensation on the basis of a published patent application and how this figure may change based on:
  - the estimated value of the invention in a specific therapeutic or treatment
  - the current competitive landscape
- Identifying whether or not limitations and caps exist
  - knowing when they apply and what they are
- Quantifying the appropriate compensation for:
  - unjust enrichment
  - destruction
  - costs and enforcement

4:30 **Caselaw Update: Emerging Trends in Foreign Life Sciences Patent Litigation**

Mustafa Safiyuddin
Chairman
Legasis Partners (Mumbai, India)

Stephan F. Jones
Partner
Baker & McKenzie (London, England)

Benjamin C. Hsing
Partner
Kaye Scholer LLP (New York, NY)

With substantial profits at stake, it is paramount to your success at trial to remain abreast of the current status of caselaw in the jurisdiction(s) where your case will be litigated.

You cannot afford to go to trial uniformed about how previous or pending cases involving life sciences patents or related patented therapies and methodologies have been decided and litigated in various foreign jurisdictions.

This session will bring you up-to-speed on the current litigation environment for life sciences patents in the following key jurisdictions:

- EU
- India
- Other emerging Asian markets

5:30 **Conference Concludes**

WEDNESDAY, DECEMBER 9, 2009 | 9:00 am – 12:00 pm *(Registration begins at 8:30 am)*

Mastering the Interplay Between Foreign Patent Law and Regulatory Requirements For Life Sciences Companies in the EU and Asia

Bert Oosting
Head, Intellectual Property & Information Technology Group, Amsterdam Office
Head, Pharmaceutical Group, Amsterdam Office
Lovells LLP (Amsterdam, Netherlands)

James M. Gould
Legal Director - Global Patent Litigation
Schering-Plough Corporation (Kenilworth, NJ)

During this session, foreign patent counsel who are also well schooled in regulatory law will provide you with a comprehensive overview of the basics of patent protection and regulatory approval necessary for the commercial viability of your life sciences product in the EU and emerging Asian jurisdictions.

Points of discussion will include:

- Available and pending remedies for enforcing intellectual property rights
  - Intellectual Property Rights Enforcement Directive (IPRED)
    - civil remedies only
  - Second Intellectual Property Rights Enforcement Director (IPRED2) *(proposed)*
    - pending directive which would allow criminal remedies aimed at ensuring the enforcement of intellectual property rights
- Exploring the interplay between patent law and regulatory requirements when there is no patent linkage, but patent law is embedded within the regulatory framework
  - Infringement of Swiss type second medical use/methods for treatment claims
    - "offering" by inclusion of the new second medical use in the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL)
    - knowing what regulatory requirements can contribute to patent infringement and what you can do to minimize downstream allegations of infringement
- Overview of key European Pharmaceutical Directives
  - 65/65/EEC1 (first European Pharmaceutical Directive – Thalidomide)
  - 75/318/EEC & 75/319/EEC (the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products)
  - 93/41/EEC (the approximation of national measures relating to the placing on the market of high- technology medicinal products, particularly those derived from biotechnology)
    - established two procedures for seeking authorisation for medicinal products ("centralized" vs. "mutual recognition")
  - 93/42/EEC (the Medical Devices Directive – harmonized the laws relating to medical devices in the EU)
  - 2001/20/EC & 2005/28/EC (the Clinical Trials Directives – implementing standards for good clinical practice in the conduct of clinical trials on medicinal products for human use)
  - 2001/83/EC (concerning provisions relating to medicinal products which directly affected the functioning of the internal market of the EU)
  - 2004/27
    - satisfying the Carve Out ("skinny label") under Article 11 vs. under the US Patent Notice System
    - meeting the research exemption under patent law vs. under the Bolar exemption
- Summary of the duties and functions of the European Medicines Agency (EMEA)
- Incorporating new clinical research requirements under the Paediatric Regulation into your R&D protocol
- Contrasting points within other key Asian jurisdictions
  - Japan - summary of the duties and functions of the Ministry of Health, Labour & Welfare
  - Korea - Considering the impact recent changes to the generic drug pricing procedure in Korea will have on brand name and generic drug competition and accounting for these changes in your advanced IP portfolio strategy

December 7 - 8, 2009 | The Carlton | New York, NY

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FOR THE U.S. LIFE SCIENCES PATENT PRACTITIONER

Strategies for Containing Costs and Maximizing IP Protection in the EU & Emerging Asian Markets

WORKSHOP

WEDNESDAY, DECEMBER 9, 2009

9:00 am – 12:00 pm

Mastering the Interplay Between Foreign Patent Law and Regulatory Requirements for Life Sciences Companies in the EU and Asia

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Registration Fee

The fee includes the conference, all program materials, continental breakfasts, lunches, refreshments and complimentary membership of the ACI Alumni program.

Payment Policy

Payment must be received in full by the conference date. All discounts will be applied to the Conference Only fee (excluding add–ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to individuals employed by the same organization.

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